U. S. Department of Health and Human Services
U. S. Department of Agriculture
U. S. Department of Veterans Affairs
U. S. Environmental Protection Agency
U. S. Department of Defense
U. S. Department of State
Executive Office of the President
January 2003; updated October 2003, October 2004, July 2006, and September 2008

Questions and Answers about Dioxins

The following questions and answers provide general information about dioxins, a complex subject. The materials presented here provide information about the Environmental Protection Agency's (EPA) 2003 draft risk assessment on dioxins (also called the dioxin reassessment) and the 2006 recommendations by the National Academy of Sciences. In addition to background information, these materials discuss possible effects of dioxin exposure in humans, include advice about consumption of food that might contain dioxins, and explain the review process for the dioxin reassessment before it is finalized. The questions and answers provided here are not comments on the scientific validity of the EPA report, nor do they indicate that the analysis or conclusions of the draft EPA dioxin reassessment are final.

The Interagency Working Group on dioxin (Dioxin IWG) prepared the questions and answers in this document. The Dioxin IWG is composed of federal agencies that address health, food, and the environmental concerns. This group is working together to ensure a coordinated federal approach to dioxin-related issues. These activities include research on dioxin exposure and effects, and coordinated efforts to measure dioxin levels in the environment and food and to reduce dioxin risks. The dioxin IWG consists of representatives from the following federal agencies:

Department of Health and Human Services (DHHS)
Department of Agriculture (USDA)
Department of Veterans Affairs (DVA)
Environmental Protection Agency (EPA)
Department of Defense
Department of State
Executive Office of the President

The questions and answers are presented in four sections:

1. General information about dioxins
2. Overview of EPA's 2003 Draft Dioxin Reassessment
3. Food safety questions and answers
4. Risk assessment questions and answers

General information about dioxins

In this section, background information about dioxins is provided to help those who would like a basic understanding of what dioxins are.

G1. What are dioxins?

Overview of the EPA 2003 Draft Dioxin Reassessment

In this section, EPA describes what is in their 2003 draft dioxin reassessment documents (referred to as EPA's 2003 draft dioxin reassessment), the NAS review process and outcomes, and EPA's planned responses to the NAS comments on the 2003 draft dioxin reassessment including EPA's plans for completing the reassessment.

Food safety questions and answers

This section answers questions dealing with food safety issues.

Risk assessment questions and answers

This section answers questions dealing with general risk assessment issues relevant to the EPA draft dioxin reassessment.

General information about dioxins

G1. What are dioxins?

"Dioxins" refers to a group of chemical compounds that share certain chemical structures and biological characteristics. Several hundred of these compounds exist and are members of three closely related families: the chlorinated dibenzo-*p*-dioxins (CDDs), chlorinated dibenzofurans (CDFs) and certain polychlorinated biphenyls (PCBs). Sometimes the term dioxin is also used to refer to the most studied and one of the most toxic dioxins, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD). CDDs and CDFs are not created intentionally, but are produced as a result of human activities. Natural processes also produce CDDs and CDFs. PCBs are manufactured products, but they are no longer produced in the United States.

Dioxins are formed as a result of combustion processes such as commercial or municipal waste incineration and from burning fuels (like wood, coal or oil). The 2003 draft dioxin reassessment makes the finding that anthropogenic (man-made) emissions dominate current releases in the United States, but acknowledges the need for more data on natural sources. Dioxins can also be formed when household trash is burned and as a result of natural processes such as forest fires. Chlorine bleaching of pulp and paper, certain types of chemical manufacturing and processing, and other industrial processes all can create small quantities of dioxins. Cigarette smoke also contains small amounts of dioxins.

Over the past decade, EPA and industry have worked together to dramatically reduce dioxin emissions. It is important to note that dioxin levels in the United States environment have been declining for the last 30 years due to reductions in manmade sources. However, dioxins break down so slowly that some of the dioxins from past releases will still be in the environment many years from now. Because dioxins are extremely persistent compounds, past releases of dioxins from both man-made and natural sources still exist in the environment. A large part of the current exposures to dioxins in the United States is due to release of man-made dioxins that occurred decades ago. Even if all human-generated dioxins were eliminated, low levels of naturally produced dioxins will remain. EPA is working with other parts of the government to look for ways to further reduce dioxin levels entering the environment and to reduce human exposure to them.

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G2. Why are people concerned about dioxins?

Dioxins from natural and anthropogenic (man-made) sources have been widely distributed throughout the environment. Almost every living creature has been exposed to dioxins (see also G9). Studies have shown that exposure to dioxins at high enough doses may cause a number of adverse health effects. The health effects associated with dioxins depend on a variety of factors including: the level of exposure, when someone was exposed, and for how long and how often. Because dioxins are so widespread, we all have some level of dioxins in our bodies.

The most common health effect in people exposed to large amounts of dioxin is chloracne. Chloracne cases have typically been the result of accidents or significant contamination events. Chloracne is a severe skin disease with acne-like lesions that occur mainly on the face and upper body. Other effects of exposure to large amounts of dioxin include skin rashes, skin discoloration, excessive body hair, and possibly mild liver damage.

One of the main concerns over health effects from dioxins is the risk of cancer in adults. Several studies suggest that workers exposed to high levels of dioxins at their workplace over many years have an increased risk of cancer. Animal studies have also shown an increased risk of cancer from long-term exposure to dioxins.

Finally, based on data from animal studies, there is some concern that exposure to low levels of dioxins over long periods (or high level exposures at sensitive times) might result in reproductive or developmental effects.

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G3. What happens to dioxins when they enter the environment?

When released into the air, some dioxins may be transported long distances. Because of this, dioxins are found in most places in the world. When dioxins are released into water, they tend to settle into sediments where they can be further transported or ingested by fish and other aquatic organisms. Dioxins decompose very slowly in the environment and can be deposited on plants and taken up by animals and aquatic organisms. Dioxins may be concentrated in the food chain so that animals have higher concentrations than plants, water, soil, or sediments. Within animals, dioxins tend to accumulate in fat.

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G4. How might I be exposed to dioxins?

Most of the population has low-level exposure to dioxins. Although dioxins are environmental contaminants, most dioxin exposure occurs through the diet, with over 95% coming through dietary intake of animal fats (see also F3 and F4). Small amounts of exposure occur from breathing air containing trace amounts of dioxins on particles and in vapor form, from inadvertent ingestion of soil containing dioxins, and from absorption through the skin contacting air, soil, or water containing minute levels of dioxins.

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G5. Do all dioxin compounds pose the same risk?

No. Different dioxin compounds have different toxicities and dioxins are most often found in mixtures rather than as single compounds in the environment. The most toxic forms of dioxin are 2,3,7,8-TCDD and 1,2,3,7,8-PeCDD. Scientists use a shorthand method for comparing the toxicity of different types or mixtures of dioxins to the toxicity of 2,3,7,8-TCDD and 1,2,3,7,8-PeCDD. This method is called the "Toxicity Equivalence" or TEQ.

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G6. Have we made progress in reducing environmental dioxins?

Yes. Dioxin levels in the United States environment have been declining for the last 30 years due to reductions in manmade sources. In fact, as a result of the efforts of EPA, state governments and industry, known and quantifiable industrial emissions of dioxin in the United States have been reduced by more than 90% from 1987 levels. However, dioxins break down so slowly that some of the dioxins from past releases will still be in the environment many years from now. Dioxins that remain in the environment from past releases are sometimes called "reservoir sources" of dioxins. Because of processes in the natural environment, dioxin levels will never go to zero.

Based on recent measurements in a few states, it appears that levels in our bodies are declining. Federal agencies are continuing to monitor to see if these trends continue. Again, because of background occurrence of dioxin in the environment, the levels will probably never go to zero.

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G7. What is meant by "natural background" and "current background" for dioxins?

In addition to manmade sources, natural processes, such as brush and forest fires, produce dioxins. The term "natural background" for dioxins refers to the dioxins that are in the environment because of these natural processes. The natural background level of dioxins cannot be directly measured. The term "current background" refers to the level of dioxin in the environment today. Current background is primarily made up of dioxins from man-made sources.

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G8. What are the major sources of dioxins?

The amounts of dioxin released from various sources have changed significantly over time. Historically, commercial or municipal waste incineration, manufacture and use of certain herbicides and chlorine bleaching of pulp and paper resulted in the major releases of dioxins to air and water. Government regulatory actions along with voluntary industry actions have resulted in dramatic reductions in each of these sources, and they are no longer major contributors of dioxins to the environment in the United States. While the United States has taken action to control this type of emission, some of these sources of

dioxin still occur elsewhere in the world. Currently, the uncontrolled burning of residential waste is thought to be the largest sources of dioxins to the environment in the United States.

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G9. How long has dioxin exposure existed?

Dioxins have been around for a long time. There are natural sources for dioxins like brush and forest fires and volcanic eruptions, although natural sources contribute little to the current background dioxin levels. As a consequence of industrialization, dioxin levels began increasing in the global environment. Declines in environmental levels began in the 1970's when dioxins were recognized as highly toxic chemicals and governments and industry took actions to prevent environmental pollution.

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G10. What is EPA doing to control dioxin releases into the environment?

Over the past few decades, EPA has aggressively looked for ways to reduce and control dioxins in the environment in the United States. Collectively, these actions have resulted in strict controls on all of the known and quantifiable major industrial sources of dioxin releases. As a result of EPA's efforts, along with efforts by state governments and private industry, known and quantifiable industrial emissions in the United States have been reduced by more than 90% from 1987 levels. For example, municipal waste combustors are estimated to have emitted collectively nearly 18 pounds of dioxin toxic equivalents in 1987, but under EPA regulations they are now expected to emit less than 1/2 ounce per year. Similarly, medical waste incinerators emitted about 5 pounds of dioxin equivalents in 1987, but under EPA regulations they now will be limited to about 1/4 ounce annual emissions. EPA has implemented similarly strict standards for other dioxin sources. Through expanded monitoring and research collaboration with the Food and Drug Administration (FDA), the Food Safety and Inspection Service (FSIS), and the Centers for Disease Control and Prevention (CDC), EPA is also making progress in characterizing additional sources.

In addition, federal agencies are already working together to coordinate federal activities related to dioxin (see also F9). Further information regarding EPA efforts to reduce dioxin emissions can be found in the fact sheets available on the Internet at cfpub.epa.gov/ncea/cfm/dioxin.cfm.

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G11. Should I (or can I) find out what my dioxin levels are?

We do not recommend dioxin testing. Tests for measuring dioxin levels in humans are not routinely available. Laboratories that offer dioxin testing generally do not have the required certification for medical testing. A person's individual dioxin level is not helpful for predicting or screening disease.

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G12. How can I reduce my personal dioxin levels?

We all have some levels of dioxins in our bodies. Dioxins have existed in our environment for a long time. Environmental dioxins have declined significantly since 1987 and recent measurements in a few states indicate that levels in our bodies are going down as well. Unfortunately, there are no safe and effective treatments to rid dioxins now in humans. Dioxins metabolize slowly over years. The best way to reduce your personal dioxins level and your potential risks from dioxins is to reduce exposure and intake of dioxins.

Although dioxins are an environmental contaminant, exposure most often occurs through the food by consumption of animal fats. Overall, the best strategy for lowering the risk of dioxins while maintaining the benefits of a good diet is to follow the recommendations in the Federal Dietary Guidelines. For most people, following Federal Dietary Guidelines will reduce fat consumption and, consequently, reduce dioxin exposure (see also G4). The dietary guidelines provide for moderate amounts of fats, which are part of a balanced diet. However, eliminating all fats is not recommended. These guidelines recommend that people choose fish, lean meat, poultry, and low or fat free (skim) dairy products and increase consumption of fruits, vegetables and whole grain products. Lean meat includes meats that are naturally lower in fat, and meat where visible fat has been trimmed. For fish and poultry, you can reduce fat by removing the skin. Reducing the amount of butter or lard used in the preparation of foods and cooking methods that reduce animal fat (such as oven broiling) will also lower the risk of exposure to dioxin. These strategies help lower the intake of saturated fats as well as reduce the level of exposure to dioxin. For information on the Federal Dietary Guidelines see www.health.gov/dietaryguidelines/.

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Overview of EPA's 2003 Draft Dioxin Reassessment

The U.S. Environmental Protection Agency (EPA) is in the final stages of completing a major scientific report entitled, *"Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds."* This report is commonly referred to as the EPA dioxin reassessment.

In April 1991, EPA announced that it would conduct a scientific reassessment of the health risks of exposure to dioxin and dioxin-like compounds. EPA decided to perform this reassessment because of significant advances in the scientific understanding of dioxin toxicity and significant new studies on its potential adverse health effects.

In 1994, EPA completed a draft of the dioxin reassessment and submitted it to the EPA's Science Advisory Board (SAB) for review. In 1995, the SAB recommended revision of two draft sections of the dioxin reassessment -- the dioxin risk characterization and the dose-response modeling chapter -- and the development of a new section on dioxin toxicity equivalence factors (TEF). Because of the complexity of the science issues related to dioxin, the SAB recommended that these three sections undergo an additional level of review by independent external peer reviewers before being brought back to the SAB for review. The three sections were:

Part II. Chapter 8: Dose-Response Modeling for 2,3,7,8-TCDD,

Part II. Chapter 9: Toxicity Equivalence Factors (TEF) for Dioxin and Related Compounds, and

Part III. Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds.

Independent external peer review, as well as public comment, was completed on each section, providing an additional level of feedback regarding the scientific credibility of the dioxin reassessment. These draft documents were revised based on peer review and public comments and submitted to the SAB for review at its November 2000 public peer review meeting.

After in-depth discussions of key science and assessment issues in the draft documents, the SAB panel approved the draft report with comment recommending that EPA address the SAB comments prior to completing the reassessment and encouraging EPA to expeditiously complete and release the reassessment, taking appropriate note of the findings and recommendations of the SAB and other public comments. On May 31, 2001, EPA received the SAB's final review report, "Dioxin Reassessment - An SAB Review of the Office of Research and Development's Reassessment of Dioxin."

The EPA modified the reassessment based on the SAB's comments and submitted the modified document to the Dioxin IWG for review and comment. Since there are differing interpretations of the science associated with the impact on human health from environmental exposure to dioxin, the Dioxin IWG recommended that the National Academy of Sciences provide an additional review to help ensure that the risk estimates contained in the draft are scientifically robust and that there is a clear delineation of all associated uncertainties. On October 29, 2003, EPA, along with the other members of the Dioxin IWG, asked the National Academy of Sciences (NAS) to review aspects of the science in EPA's draft dioxin reassessment and on October 15, 2004, EPA sent a revised draft of the dioxin reassessment to the NAS for their review.

On July 11, 2006, the NAS released the report of their review of EPA's 2003 draft dioxin reassessment. The NAS identified three areas that required substantial improvement to support a scientifically robust risk characterization. These three areas were: 1) justification of approaches to dose-response modeling for cancer and non-cancer endpoints, 2) transparency and clarity in selection of key data sets for analysis, and 3) transparency, thoroughness, and clarity in quantitative uncertainty analysis. The NAS provided EPA with recommendations to address their key concerns. Now that the NAS has completed their review of the Reassessment, the EPA will respond to the NAS comments on the dose-response assessment for 2,3,7,8-TCDD and revise its exposure assessment for dioxin and dioxin-like compounds.

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O1. What are the elements of the 2003 draft dioxin reassessment provided to the NAS (2003 NAS review draft)?

The NAS review draft of the dioxin reassessment consists of three parts. *Part I: Estimating Exposure to Dioxin-Like Compounds* includes three volumes that focus on sources, levels of dioxin-like compounds in environmental media, and human exposures. *Part II: Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* consists of two volumes that include information on critical human health end points, mode of action, pharmacokinetics, dose-response, and TEFs. *Part II has nine chapters. Part III: Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* is intended as a stand-

alone document. Part III summarizes the overall conclusions of the reassessment. This part describes key findings pertinent to the potential hazards and risks of dioxins, including a discussion of all important assumptions and uncertainties.

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O2. Why does the 2003 draft dioxin reassessment (NAS review draft) estimate of potential risk from dioxins differ from that in the 2000 draft?

EPA has been evaluating the health effects of environmental exposures to dioxins since 1980. The findings of the 2003 draft were not significantly different from those of the 2000 draft, released for review by the EPA Science Advisory Board (SAB). The 2003 NAS review draft reflected changes and clarifications in response to the SAB's comments as well as an expansion of the quantity and quality of dioxin data, in addition to refinements in how to calculate dioxin risk. The 2003 draft dioxin reassessment had an expanded analysis of background exposure, with a more current estimate of background exposure from diet. The 2003 draft also included an expanded analysis of data on whether dioxin's non-cancer effects might occur at or near doses to which the population is exposed, providing for a more robust evaluation of non-cancer effects based on body burden.

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O3. What is the status and next step regarding the dioxin reassessment?

Because the assessment is of interest to various parts of the government, EPA continues to consult with the Dioxin IWG on its draft dioxin reassessment. EPA, along with other members of the Dioxin IWG, asked the National Academy of Sciences to provide an additional review to help ensure that the risk estimates contained in the 2003 draft were scientifically robust and that there is a clear delineation of all associated uncertainties. Now that the NAS has completed its review EPA will respond to the NAS comments through a technical response document. In order to prepare this response, EPA will identify and summarize studies published since the last reassessment relevant to important science issues. EPA will then select the key studies and justify the selection of those studies. The draft technical response document will include development of draft cancer and non-cancer dose-response models, and quantitative uncertainty analyses.

The response document will be reviewed internally by the EPA, by the Dioxin IWG, and by an expert science committee formed by the SAB under the Federal Advisory Council Act (FACA). EPA will obtain technical input and review from internal EPA reviewers, the Dioxin IWG, and the SAB expert committee. The FACA panel will provide continuous advice, review and consultation on the workplan and workshops, and will conduct the final independent expert peer review of the draft technical response document to the NAS comments on the EPA's 2003 draft dioxin reassessment. In addition, as with other EPA human health assessments, a summary of the human health risk information for 2,3,7,8-TCDD will be included on EPA's Integrated Risk Information System (IRIS). Opportunities will be provided for public review and comment throughout this process (see also O10, 11, 12 and 13).

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O4. Who wrote the 2003 draft dioxin reassessment?

The dioxin reassessment is led by EPA's National Center for Environmental Assessment (NCEA), a part of the Office of Research and Development. The draft dioxin reassessment was developed over many years with the participation of scientific experts in EPA, the National Institutes of Health's National Institute of Environmental Health Sciences, and other federal agencies, as well as scientific experts in the private sector and academia.

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O5. What affected the timeline for EPA to develop the dioxin reassessment?

Development of the dioxin reassessment has taken longer than expected. It took substantial time to collect, assess, and portray in the document the significant and latest evolving data on dioxin. In addition, there has been significant controversy surrounding the science of dioxin. EPA has been rigorous and thorough throughout the development of the draft reassessment to ensure that it has been responsive to both scientific peer reviews and extensive public consultation and comment. In crafting the final reassessment, EPA must respond to the substantive and complex review comments and incorporate the most recent scientific findings. This process will ultimately benefit the American public by providing a sound scientific basis for future risk management decisions.

It is important to note that while the reassessment has been underway, EPA and other federal agencies have not stopped efforts to reduce dioxin emissions to the environment. EPA initiated control programs for most known major industrial sources of dioxin including municipal waste incinerators, medical waste incinerators, hazardous waste incinerators, boilers and industrial furnaces, and chlorine bleaching pulp and paper mills. EPA continues to make significant strides in the reduction of dioxin-containing emissions through regulatory action based on available control technology and through voluntary action by involved industries. FDA and FSIS have conducted studies on various foods to monitor the presence of dioxins.

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O6. Why did the NAS review EPA's 2003 draft dioxin reassessment?

EPA, along with other members of the Dioxin IWG, asked the NAS to review the data and analyses presented in the draft reassessment. The NAS review will assist the Dioxin IWG in properly characterizing the uncertainties associated with the draft report and in ensuring that the risk estimates contained in this assessment are scientifically robust. Further information can be obtained at http://www8.nationalacademies.org/cp/projectview.aspx?key=103.

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O7. How can I get a copy of the most recent draft of the dioxin reassessment and the NAS 2006 review report?

The easiest way to obtain a copy of the draft reassessment is at:

http://cfpub.epa.gov/ncea/cfm/dioxin.cfm.
The NAS 2006 review report is available at: http://www.nap.edu/catalog.php?record_id=11688.

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O8. Does the 2003 draft dioxin reassessment reflect the position of the federal government?

The document sent to the NAS is a draft for review and it does not represent the final position of EPA or of the federal government. Furthermore, the draft conclusions and draft science policy decisions in the dioxin reassessment are EPA's alone and do not represent consensus by all agencies in the federal government and are intended to address questions related to EPA's statutory mandates. Individual IWG agencies have been encouraged to provide additional data and analysis as they see appropriate to clarify particular issues relevant to their science policy decisions and statutory mandates.

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O9. Was the 2003 draft dioxin reassessment sent to the NAS fully up-to-date?

Due to the review and drafting process since the release of the 2000 SAB Review draft of the dioxin reassessment, the NAS review draft represents analysis of data and literature of varying dates of completion. For example, data and literature included for most of the emissions inventory chapters of Part I Volume 1 ends prior to 2000 while some sections (for example Part I Volume 2 Chapter 3, and Part II Chapter 9) include literature and analyses covering up until 2001. Literature and analyses covered for Part III extends for the most part through about October 2003, with some additional citations and analysis through October 2004. The additional citations from 2004 are of a "notes added in proof" nature to clarify key concepts. Now that the NAS review has been completed, the Agency intends to add additional data and literature to address the review comments and to add any more recent, critical citations. The NAS was charged to consider all available published literature, including those available since December 2003, in their 2005/2006 review of the draft dioxin reassessment.

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O10. What were the major recommendations of the NAS July 11, 2006, report to the EPA?

The NAS report entitled, *Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment (July 11, 2006)*, describes the reassessment as very comprehensive in its review and analysis of the extensive scientific literature on TCDD, other dioxins, and dioxin-like compounds (DLCs). It provides guidance to EPA on how the agency could improve the scientific robustness and clarity of the 2003 draft dioxin reassessment. The NAS identified three areas that required substantial improvement to support a scientifically robust risk characterization. These three areas were: 1) justification of approaches to dose-response modeling for cancer and non-cancer endpoints, 2) transparency and clarity in selection of key data sets for analysis, and 3) transparency, thoroughness, and clarity in quantitative uncertainty analysis. The NAS provided EPA with recommendations to address their key concerns. The full NAS report including recommendations is available at: http://www.nap.edu/catalog.php?record_id=11688.

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O11. What is the process that EPA will use to respond to the NAS recommendations?

EPA's response to the NAS recommendations for the dioxin reassessment is of high interest to many stakeholder groups representing a wide variety of views. From the beginning of the dioxin reassessment activity, EPA has followed an open, transparent and participatory process in the development of the reassessment. EPA is committed to this open and transparent process as it now focuses on developing its response to the NAS recommendations. Thus, the general principles of this next major stage process will be to use the best, most current science, to engage early and often with stakeholders, and to maximize transparency by holding public workshops. Also, technical scientific review will be obtained from scientists in EPA, as well as review by scientists in other federal agencies. In addition, an independent external peer review will be conducted that will include an opportunity for public review and comment.

One of the first steps in the process will be to establish a panel of external experts comprised of scientists in various scientific disciplines appropriate to the dioxin dose-response and exposure assessment activities. This panel will be convened by EPA's Science Advisory Board (SAB) under the Federal Advisory Committee Act (FACA). EPA's independent SAB, also convened under FACA, is the Agency's established process for obtaining comment and review on important EPA science products. The FACA process is a long standing and successful mechanism for obtaining independent high quality advice from leading world experts. The FACA panel will be engaged throughout the reassessment process to provide input on the workplan, workshops and intermediate products, in addition to providing independent peer review of the draft technical response to the NAS recommendations and the human health risk information summary file that will be included on EPA's Integrated Risk Information System (IRIS). Under FACA rules, all meetings are conducted in public and are open to public input.

The purposes of this FACA panel will be to provide continuous advice, review, and consultation and serve as the independent external peer review panel for draft products. A Federal Register notice will be published soliciting nominations of nationally recognized scientists for membership consideration on this panel. In addition, EPA expects to hold a public meeting that will also be announced in the Federal Register to discuss the agency's plan for addressing the NAS recommendations. This public meeting will have invited experts who will be asked to identify the important science issues required to address NAS concerns and identify new studies, and sources of information.

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O12. What will be the expected products resulting from EPA's plan to respond to the NAS recommendations?

The expected products are: 1) EPA's response to the NAS recommendations on dose-response assessment for cancer and non-cancer endpoints associated with dioxin exposures, including a quantitative uncertainty analysis; 2) EPA Policy Paper on use of Toxicity Equivalence Factors (TEFs) for dioxin-like compounds; and 3) update of the characterization of background exposures.

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O13. How long will it take EPA to respond to the NAS recommendations?

EPA is committed to an open, transparent, and participatory process for this high profile, significant, and complex response to the NAS. EPA must assure that the draft responses are subjected to rigorous independent external peer review and public review and comment and that the resulting response is of the highest scientific quality. EPA estimates that the response will be completed in 2012.

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Food safety questions and answers

Exposure to dioxins in the food supply stems from environmental sources. Dioxins break down very slowly in the environment and can be deposited on plants and taken up by animals and aquatic organisms. Dioxins may be concentrated in the food chain so that animals have higher concentrations than the plants, water, soil, or sediments around them. Within animals, dioxins tend to accumulate in fat.

Federal agencies have been aware of very low levels of dioxins in foods since the 1970's and have been increasing their monitoring since the late 1990's, as technology to measure this group of compounds at very low levels has improved. The presence of dioxins in foods is not new, nor is it unique to the U.S. food supply. However, dioxins in food are at such low levels that it is not practical to routinely measure them even using current testing methods. The Food and Drug Administration (FDA) and USDA's Food Safety and Inspection Service (FSIS) are exploring ways to address these issues in collaboration with EPA, including broadening the existing monitoring program for dioxins in the U.S. food and feed supply. To date, the FDA monitoring of dairy products and fish shows that when detectable levels are found they are generally consistent with EPA estimates for background occurrence of dioxins (see also G7). The contribution of dioxins to dietary exposure and the possible introduction via the use of particular feed components was identified by the National Academy of Sciences (NAS) Committee on the Implications of Dioxin in the Food Supply. The NAS report, issued on July 1, 2003, entitled "Dioxins and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure," was commissioned by the Dioxin IWG. We are continuing our efforts to reduce dioxin levels even further both in the environment and therefore in foods.

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F1. What levels of dietary dioxin exposure cause adverse health effects in humans?

Known incidents of high dioxin levels in humans have resulted from accidental exposures that are not typical with dietary exposures. Despite a large body of research and data collection, there are numerous questions and uncertainties regarding scientific data on and analysis of dioxin risk. These uncertainties are unlikely to be resolved in the near future.

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F2. Is the food supply safe?

The U.S. food supply is among the safest and most nutritious in the world. While the

federal food and environmental agencies are concerned about dioxin, the draft report does not change the government's view of the overall safety of the food supply in this country. Maintaining the safety of the food supply is a top priority of the federal government.

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F3. Should I stop eating particular foods?

No, we do not recommend avoiding particular foods because of dioxins. The EPA's 2003 draft dioxin reassessment indicates that following the science-based advice in the Dietary Guidelines for Americans will also likely help individuals lower their risk of exposure to dioxins. These guidelines include the recommendations to choose meat and dairy products that are lean, low fat, or fat free and to increase consumption of fruits, vegetable, and whole grain products. Meat, milk, and fish are important sources of nutrients for the American public and an appropriate part of a balanced diet. Milk is a major source of calcium, vitamins A and D, and riboflavin; meat is an important source of iron, zinc and several B-vitamins; fish provides beneficial fatty acids as well as certain vitamins and minerals. Each of these foods provides high quality protein in the diet. Lean meat includes meats that are naturally lower in fat, and meat where visible fat has been trimmed. For fish and poultry you can reduce fat by removing the skin. Reducing the amount of butter or lard used in the preparation of foods and cooking methods that reduce fat (such as oven broiling) will also lower the risk of exposure to dioxin. These strategies help lower the intake of saturated fats as well as reduce the risk of exposure to dioxin. Similarly, the 2003 NAS report titled "Dioxins and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure" identified options to be considered to reduce dioxin exposure through food-consumption pathways. One of these options was promoting changes in dietary consumption patterns of the general population that more closely conform to recommendations to reduce consumption of animal fats, such as the recommendations of the Dietary Guidelines for Americans. For information on the Federal Dietary Guidelines see www.health.gov/dietaryguidelines/.

You should also pay attention to local fishing advisories for fish that you catch yourself (see also F6). Fishing advisories may exist that provide recommended consumption rates of particular kinds of fish from particular water bodies where local contamination has occurred. If you do not know whether a water body that you fish in is covered under a fishing advisory, call your local or state health or environmental protection department and ask for their advice. (They are listed in the blue pages of your local telephone directory.) Ask them if there are advisories on the kinds or sizes of fish that should not be eaten from the water body. You can also ask about fishing advisories at local sporting goods or bait shops where fishing licenses are sold.

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F4. Should I reduce my fat intake?

For most people, adjusting their diet to fall within the Federal Dietary Guidelines will result in multiple health benefits, including reduced dioxin exposure. The dietary guidelines provide the best scientifically based advice on what constitutes a healthy diet and provide guidance on how to plan a varied diet choosing individual foods from a number of food groups. These groups include whole grain products such as breads and

cereals, fruits and vegetables, lean meats, and low-fat dairy products. However, some people consume more foods high in saturated fats (meat and dairy) than is recommended in the Dietary Guidelines. For these people, there are well-known and significant health benefits from reducing saturated fat intake that go beyond the potential risks of dioxin. The Dietary Guidelines, however, do not recommend that people avoid all fats, as fats are an important part of balanced nutrition.

We need a certain amount of fat for a healthy, balanced diet. Fats supply energy and essential fatty acids, and they help the body absorb fat-soluble vitamins (A, D, E, and K). You need some fat in the food you eat. The federal Dietary Guidelines recommend that fat intake be no more than 20 to 35% of your total energy intake, with less than 10% coming from saturated fats. For a person who consumes 2000 calories this means a total fat intake of less than 65 grams, including 20 grams or less of saturated fat. See the Nutrition Facts Label on food products for more information on fat content of food items. The Dietary Guidelines do not recommend that you avoid all fats, but recommend an appropriate level of lean meats and low or fat-free dairy products and recommend reducing the use of spreads or cooking fat made from animal fat. This advice regarding saturated fats is consistent with a strategy to reduce dioxin exposure.

For information on the Nutrition Facts Labels see http://www.cfsan.fda.gov/label.html.

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F5. Can I cook the dioxins out? Or wash them off?

Good food safety practices like washing food and countertops will reduce risk from bacterial infection, but they cannot reduce dioxin levels. Methods that keep fat at a minimum in the food you eat (such as trimming fat and broiling) may help to reduce dioxin exposure.

For more discussion of food safety practices, see http://www.foodsafety.gov/~fsg/fsgfaq.html.

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F6. Does the government monitor food for dioxins?

The government monitors potential dietary sources of dioxins, primarily foods that contain animal fat. The goal of this monitoring is to find any unusually high dioxin levels in foods and then work to determine the dioxin sources for those high levels so that they can be controlled or eliminated before entering the food supply.

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F7. What kinds of foods are tested, how often, and in how many locations?

FDA and USDA's Food Safety and Inspection Service (FSIS) monitoring has been focused on food products in which there is a greater potential to contain dioxins. In the past, it was more difficult to detect or monitor the low levels of dioxins in foods. Recent improvements in dioxin testing methods have allowed the federal government to expand its monitoring efforts. In addition, feed components have emerged as an important target

to predict how animal feed may contribute to the dioxin levels in some foods.

FSIS began to monitor dioxins in domestically produced beef, pork, and poultry products with a survey of each of these products being conducted between 1994 and 1996 (163 total samples). A larger survey of these products was conducted in 2002-2003 (510 total samples). Further, FSIS is in the midst of its current survey of over 500 beef, pork, and poultry samples for dioxins (2007-2008).

Since about 1995, FDA dioxin monitoring has involved several hundred samples a year, primarily of fish and dairy products from grocery stores and distribution centers across the country. To date the FDA monitoring of dairy products and fish shows that when detectable levels are found they are generally consistent with EPA estimates for background occurrence of dioxins (see also G7).

In 1999, FDA began annual monitoring for dioxins as part of FDA's Total Diet Study (TDS). TDS is a yearly program that determines levels of various pesticide residues, contaminants, and nutrients in foods.

In addition to the TDS samples, FDA conducts additional non-TDS (targeted) sampling of food and animal feed in an effort to gather additional information on dioxin. FDA collected approximately 550 food and feed samples in 2001 and approximately 1,050 food and feed samples in 2002 for dioxin analysis. FDA expanded the program to approximately 1,700 food and feed samples in 2003, 2004 and 2005, and collected and analyzed approximately 1,100 food and feed samples in 2006, 2007 and 2008. FDA plans to include additional analytes (nine dioxin-like and non-dioxin-like PCBs congeners) in select samples in 2009.

FDA has posted data for dioxin levels in TDS and non-TDS samples and posted exposure estimates using these results. For more information about FDA's posted data for dioxin levels in TDS and non-TDS samples and exposure estimates see http://www.cfsan.fda.gov/~lrd/dioxdata.html. For more information about FDA's TDS see http://www.cfsan.fda.gov/~comm/tds-toc.html

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F8. How do dioxin levels now found in food compare to the incidents of dioxin contamination that have been in the news in previous years?

To date the FDA monitoring of dairy products and fish shows that when detectable levels are found they are generally consistent with EPA estimates for background occurrence of dioxins (see also G7). It is also important to note that known and quantifiable industrial emissions of dioxins in the United States have been reduced significantly since 1987. In addition, recent measurements from a few states show that dioxin levels in our bodies have also been reduced.

There were however, two incidents involving dioxin in food in past years that received national and international attention. In both incidents, the dioxin levels were higher than background levels typically seen in foods tested by FDA or FSIS. In the first incident in 1997, elevated levels of dioxins were found in some farm-raised fish and poultry products. The levels in fish, poultry, and eggs during this incident were about 10 times higher than background levels. An investigation was quickly launched by FDA, FSIS,

and EPA. That investigation discovered that particular clay from one mine in Mississippi used as an additive to animal feed was responsible for the higher dioxin levels. The clay, which appears to have naturally occurring dioxins, was withdrawn from use as an animal feed ingredient. The government is continuing to monitor these foods and will address any situations identified.

In the second incident in 1999, elevated levels of dioxins were discovered in some Belgian animal products, and the source of the dioxins was traced to animal feeds from a particular source. The U.S. government stopped the import of certain foods from a number of European countries until it could be either established that dioxin contaminated feeds were not fed to the slaughtered animals, or that food derived from the slaughtered animals did not contain elevated dioxins. The levels of dioxins in this incident were a hundred or more times higher than what the current background levels are in similar foods in the United States.

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F9. What is the federal government doing to reduce dioxin levels in food?

Relevant federal agencies have taken a number of actions to reduce dioxin levels in food. EPA has taken aggressive actions to reduce dioxin emissions into the environmental by placing strict regulatory controls on all of the major industrial sources of dioxins. The known, quantifiable industrial emissions have been reduced by more the 90% from their levels in the 1980's as a result of EPA's efforts, along with efforts by state government and private industry.

In the long-term, efforts to reduce dioxin in the environment should also reduce dioxin levels in the food supply. Federal agencies have been monitoring the levels in foods and conducting an investigation whenever a particular food has dioxin levels detected over the background levels in that food. If the investigation determines a specific source of the increased dioxins, the Food and Drug Administration and the Food Safety Inspection Service take action to remove that source where practicable.

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F10. Given that studies have shown that dioxin is in breast milk, should I nurse my infant?

Yes. Studies consistently show that breastfed infants are healthier than formula fed infants. This statement is even more relevant now than in the past, when the levels of dioxin in breast milk were higher than they are today.

There are overwhelming benefits of breastfeeding both for the mother and her infant. The American Academy of Pediatrics and many other professional organizations have concluded that the benefits of breastfeeding far outweigh the potential effects of dioxin in breast milk. Breast milk is known to be the most complete form of nutrition for infants, with benefits for infant health, growth, immunity, and development. The benefits of breastfeeding for children include fewer cases and less severity of diarrhea, respiratory infections, ear infections, and meningitis, among others. Breastfeeding may also reduce the risk of sudden infant death syndrome and may lower rates of childhood cancer.

In addition to the benefits for children, breastfeeding also has benefits for mothers.

Breastfeeding has been shown to reduce postpartum bleeding, promote earlier return to pre-pregnancy weight, and reduce the risk of breast cancer.

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Risk assessment questions and answers

The purpose of EPA's 2003 draft dioxin reassessment is to estimate the potential harm from dioxin exposure. There are significant scientific uncertainties associated with our understanding of the adverse health effects of dioxin and the quantitative relationships between dioxin exposures and the risk of those effects. At present, scientists cannot provide highly reliable assessments of dioxin health risks. In conducting its risk assessment, EPA has tended to treat scientific uncertainties in a cautious way, to avoid understating risks to health. Assessments like this help us to compare risks from dioxins to risks posed by other contaminants and determine whether there is a need to reduce the potential risks identified for dioxins. EPA made assumptions about things such as whether exposures to workers in a factory are the same as exposures from food, and whether the higher doses received by factory workers for a short time inform us about what would happen at the lower doses we get from the diet over a long time. Risk assessments like the EPA 2003 draft dioxin reassessment do not predict actual health risks for an individual or tell us how often health effects will actually occur in the population. The approach used by EPA in the 2003 draft dioxin reassessment is a commonly accepted practice by federal and state health agencies.

R1. Did EPA provide a scientifically conservative estimate in its 2003 draft dioxin reassessment?

The purpose of a risk assessment is to estimate the potential risk from exposure to a particular substance, in this case dioxins. EPA wants to produce a scientifically credible estimate of how high the possible risks from exposures to dioxins might be. Care was taken to not underestimate potential risk. For example, EPA made assumptions about how mixtures of chemicals behave in the body, about how data from animal studies and limited observations in groups of humans might relate to the general population, and about whether certain individuals in the population might be particularly sensitive to the exposure.

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R2. EPA's 2003 draft dioxin assessment provides a scientifically conservative cancer risk estimate, but what is the actual risk?

It is not yet possible to know the actual risk posed by dioxins in the environment. EPA's draft 2003 draft dioxin reassessment presents an upper bound estimate of potential cancer risk. The actual risk for most individuals is expected to be lower and may be zero for some individuals. The quantitative uncertainty analysis that EPA will conduct at the recommendation of the NAS will provide more information about the range of potential risk from dioxin exposure.

It is important to realize that assessments like EPA's do not predict actual health effect risk for any one person, or health effect rates in the population. EPA uses its best judgment with the available data and standard approaches in reaching its conclusions about potential risks. Despite a large body of research and data collection, there are

numerous questions and uncertainties regarding scientific data on and analysis of dioxin risk. These uncertainties are unlikely to be resolved in the near future.

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R3. In evaluating potential risks for the U.S. population, why did EPA use data from other countries?

Dioxins are found in the environment around the world. EPA wanted to use all available scientifically valid data, no matter where the work was done. The 2003 draft dioxin reassessment primarily used North American data to estimate emission sources in our region, environmental levels, dietary levels and levels of exposure to the U.S. population. In evaluating the effect of exposure on human populations or on animals, EPA evaluated studies from around the world.

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R4. What are possible next steps for the Dioxin IWG?

The Dioxin IWG will continue to coordinate agency activities associated with dioxin. The IWG will continue to assess the need for additional dioxin risk management activities across the Federal government based on the findings of the reassessment.

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Pesticides, Metals, Chemical Contaminants, and Natural Toxins

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