FINDINGS REPORT

Development of an Analytic Approach to Determine how the Environmental Protection Agency's Integrated Risk Information System is used by non EPA Decision Makers

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I. Executive Summary

The United States Environmental Protection Agency's (EPA) contracted with ENVIRON International Corporation to develop an analytical approach to determine how the Integrated Risk Information System (IRIS) is used by non EPA decision makers and IRIS customers in general. The approach developed and used by ENVIRON was to identify categories of IRIS customers and determine how representatives within the categories use IRIS. Information was collected in several ways, and the primary method consisted of interviews with representative customers from nine different user categories. The information collected during those nine interviews provides the bulk of the findings presented in this report.

It is important to note that the data set collected for this report is limited. The focus of the analysis was to collect representative information across a broad spectrum of IRIS customers, not to conduct a comprehensive survey. Accordingly, this report can only present the views of a small minority of users. However, the customers interviewed characterized themselves as the most frequent users within their company, agency, academic program, trade association, or organization. Thus, this report presents the views of a small but highly significant sampling of IRIS customers.

The nine formal interviews and supplemental discussions with other customers resulted in some very evident and easily discernable findings. The interviewees were remarkably consistent in their thoughts on IRIS and therefore it was easy to develop conclusions. IRIS is accessed by hundreds of people daily, from all over the world, with undoubtedly differing technical training and skills. However, frequent users, particularly those who use IRIS in their every day work lives, are very similar in how and why they use IRIS. For example, frequent users typically have training in toxicology, chemistry and related scientific disciplines.

Frequent customers use IRIS for two fundamental and related purposes: 1) as a source of comprehensive information on a chemical; and 2) to seek information for use for regulatory purposes. Customers who use IRIS for general information often rely upon other databases to complement an IRIS file. However, for domestic regulatory purposes there is no satisfactory alternative to IRIS. Other databases exist that can provide some assistance, but there is no substitute for an IRIS file for regulatory support. Customers understand the necessity of IRIS –or a similar product/service-- in the decision making process. They know from experience that the existence of a peer reviewed, EPA consensus database makes for quicker and better informed decisions.

IRIS is a "brand" name recognized globally as the repository of EPA chemical risk assessment information and practices. IRIS as a brand is consistently characterized in a compelling and precise manner: "a peer reviewed database with Agency consensus positions." This view – and often those exact words-- was expressed by customers from

government, industry, academia, non-governmental organizations (NGOs) and research organizations, both U.S and foreign based.

Frequent customers are also consistent in their complaint about the "slow pace" of finalizing new chemical files and updating old files. Because IRIS is so critical to the regulatory process, the absence of a file for a chemical of concern results in uncertainty and creates additional work for all parties. Most customers interviewed do not understand the IRIS file development and approval process and therefore do not understand why it takes so long to issue a product they are dependent upon.

Frequent customers find IRIS easy to use and therefore are not in need of training. However, they uniformly expressed interest in having opportunities to interact with ORD staff to discuss issues and concerns which they believe are of mutual interest. Many users recommended that an institutionalized dialogue mechanism be established which would allow for two way communication and provide a valuable feedback mechanism. Customers feel a loyalty to IRIS and want to work with the Agency to enhance the value of a necessary and valuable product.

II. Introduction

The United States Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) program provides a database containing Agency consensus scientific positions on potential adverse human health effects that may result from chronic (or lifetime) exposure to chemicals in the environment. IRIS provides essential support in making decisions for addressing and responding to Agency regulatory and clean up programs. In addition, because it is one of the premier toxicological databases in the world, IRIS is used by a wide variety of non-EPA customers. EPA knows that IRIS is widely used, but does not have a full understanding of the categories of users, how customers use IRIS in making decisions, and the quality of the IRIS use experience.

The purpose of this project was to identify categories of IRIS customers (excluding EPA users) and determine how representatives within the categories use IRIS. The key tasks included the identification and categorization of user groups; the development of an analytical approach for determining uses; and an analysis of how well the current process meets the needs of representative customers.

III. Information Collection

Information was collected through two mechanisms; 1) indirectly by accessing potential IRIS customer web sites; listening to or reading presentations related to IRIS and risk assessment; and reading position statements, guidance material and related reports; and 2) directly through the conduct of nine interviews with representative IRIS customers from different user categories. The information collected during the nine interviews provides the bulk of the findings presented in this report. In addition, several other customers requested the opportunity to speak about their IRIS use experience. These customers had

heard about the project and wanted to express their views concerning IRIS. For example, information was collected indirectly by participating in an Environmental Council of the States (ECOS) conference call on risk assessment. Several state scientists on the call asked how they could communicate their thoughts on IRIS; it was explained that there would be one official interview with a representative state customer, but that the thoughts of other state agencies would be noted. Thus, this report presents findings and analysis from nine official interviews, but each of the interviews has been supplemented by information from other customers within the user category.

The purpose of the interviews was to collect information from frequent users who are representative of a customer category. The intent was not to collect "official" positions on IRIS; to the contrary, it was important that interviewees spoke freely. Thus, the names and affiliations of the interviewees are not identified; however, interviewees and their organizations are characterized. For example, an interviewee may be described as a toxicologist working for a large chemical manufacturing company; or a scientist who directs a science and research office in a state regulatory agency which has the resources to conduct chemical specific risk assessments.

A. User Categories

The first step in the project was to develop a list of categories of frequent users. The approach was to develop an initial draft list based on indirect information collection and then modify the list as additional information was collected. The nine categories identified are certainly justifiable, however; it is clear that some of the categories warrant identification of several layers of sub-categories. This is most notable for state agencies. For example, all state environmental regulatory agencies use IRIS in similar manners; but those agencies with toxicologists on staff are able to critically evaluate the quality of an IRIS file. They are also better able to conduct risk assessments and arrive at numerical values, than are agencies with limited science resources.

The nine categories of IRIS customer groups used for this project are the following:

1. State environmental regulatory agencies;
2. Chemical manufacturers;
3. Downstream chemical users;
4. Federal agencies (non-EPA)
5. Trade associations;
6. Research organizations;
7. Academic institutions;
8. Non-Government Organizations; and,
9. Non United Sates frequent users.

Some of the categories identified are more significant than others because there are more users within the category and they are more dependent upon IRIS in order to do their job. For example, IRIS is essential to the operations of all state environmental agencies. They depend upon information from IRIS to make regulatory decisions; it is the most credible and recognized source of information. IRIS is of similar importance to industrial companies and other potential responsible parties, again because IRIS is used to make regulatory decisions. IRIS is not as critical to other categories, such as research organizations and academic institutions; they use and value IRIS, but in the absence of an IRIS file they can turn to other sources of information.

B. Interview Process

It was determined that the most effective manner to collect information was through face to face or phone interviews with representatives from user categories. The interviews were supplemented by email correspondence, particularly following or preceding the interviews. The approach was to contact a representative user, describe the project, and schedule a visit or phone call. Many of the interviewees requested that their colleagues be part of the interview process because of their interest in IRIS. A face-to-face interview was typically scheduled for one hour; two hours were scheduled if there were four or more people were interviewed. Phone interviews generally lasted no more than one hour.

The representatives interviewed were always frequent users of IRIS, and usually were the most frequent users within their company, organization, or agency.

C. General Findings

The nine formal interviews and supplemental discussions with other customers resulted in some very evident and easily discernable findings. The interviewees were remarkably consistent in their thoughts on IRIS and therefore it was easy to draw conclusions. The following are the key findings uncovered during the interview process; more detailed findings are presented later in the report, organized by the nine customer categories.

- IRIS is widely used by a variety of customers around the world. However, frequent customers, who use IRIS primarily for work purposes, typically have training in toxicology, chemistry and related scientific disciplines.

- Frequent IRIS customers work for various organizations and institutions, including federal and state government, foreign governments, regional and global governmental organizations, industries that manufacture or use chemicals, trade associations representing those industries, consulting firms, academia, research

organizations, and non-government organizations focused on environmental health issues.

- Frequent customers want to talk about their IRIS experience; they asked to be involved in this project and they uniformly expressed interest in talking to fellow frequent customers as well as ORD staff.

- Frequent customers use IRIS in two fundamental and related manners: as a source of comprehensive information on a chemical; and to seek information for use for regulatory purposes. All the customers interviewed use IRIS as a principal source of information for a chemical of concern. Those who also use IRIS for regulatory purposes typically work for a government agency or a responsible party; but numerical values presented in IRIS are of interest to most frequent customers.

- Frequent customers use IRIS as a starting point for accessing a variety of EPA risk assessment services.

- Customers who use IRIS for general information often rely upon other databases to complement an IRIS file. However, for domestic regulatory purposes there is no satisfactory alternative to IRIS. Other databases exist which can provide some assistance, but there is no substitute for an IRIS file.

- Customers understand the necessity of IRIS –or a similar product/service-- in the decision making process. They know from experience that the existence of a peer reviewed, EPA consensus database makes for quicker and better informed decisions.

- IRIS is a "brand" name recognized globally as the repository of chemical risk assessment information and practices. All frequent customers know that IRIS is a product managed by the US EPA; but they tend to view IRIS as the federal chemical risk assessment database, not as an ORD or NCEA product. Most importantly, IRIS as a brand is consistently characterized in a compelling and precise manner: "a peer reviewed database with Agency consensus positions."

- IRIS is often known by government decision makers who are not frequent customers and may never have accessed the database. At times, officials such as a secretary of a state environmental regulatory office will ask "what does IRIS say" about the chemical of concern, meaning "what is the EPA position."

- Frequent customers find it easy to maneuver through the database, and understand the information presented. Therefore, training is not necessary in order to use IRIS, but frequent users would welcome "discussion" opportunities.

- Many frequent customers view IRIS files critically; assessing the completeness of the data (in comparison with other files) and the date of the file. If a file is

considered "dated" the frequent user is likely to more seriously consider other sources of information. However, typically, even a dated IRIS file is preferred to other sources of information.

- The biggest concern about IRIS is the "slow pace" of finalizing new chemical files and updating old files. Because IRIS is so critical to the regulatory process, the absence of an IRIS file for a chemical of concern results in uncertainty and creates additional work for all parties.

- Customers desire additional and more accurate information on the status of existing and projected IRIS files. They like the idea of the IRIS Track but many customers question the accuracy of IRIS Track. Several customers expressed interest in a more descriptive IRIS Track; one that would describe the process hurdles (awaiting interagency discussion or OMB approval) as well as a listing of information sources used in conducting assessments and the key scientific issues to be addressed.

- Customers dependent on IRIS for regulatory decisions, such as state agencies, would appreciate informal yet informative briefings on files under development. These customers are not asking for access to draft files or draft risk assessments; rather they would like the opportunity to have a dialogue with fellow professionals engaged in similar assessments. This is particularly the case when a state agency must make a decision prior to the issuance of a final IRIS file.

- Some customers expect that all available information relating to a chemical will be referenced in the IRIS file, regardless of the date of the file. These customers assume that information is continually added to a file; such as recent peer reviewed studies, or EPA risk management initiatives. They view the IRIS file as the place to find all information on the chemical of concern.

- Conversely, many IRIS customers are not aware of the many recent upgrades to the web site; on several occasions interviewees suggested that ORD add a service or feature to IRIS which in fact already exists.

- Most customers interviewed do not understand the IRIS file development and approval process. Most are not familiar with the mandate or expectations of the Office of Management and Budget or an interagency review body. They have a better grasp of the role of National Research Council panels and reports but are uncertain as to why and how such panels are formed.

- A concern expressed by industry is that the European Union is increasingly involved in risk assessment-related activities -- which could have global implications – and is doing so without the benefit of a U.S. voice. Although regulated parties may challenge some IRIS values, they believe that IRIS, with a

transparent review and comment opportunity, should be viewed as a global example.

- IRIS is seldom, if ever, used by frequent customers to educate the general public or citizens concerned about a specific chemical or pollution source. Rather the frequent customer will use IRIS to become knowledgeable and develop an educational presentation. Seldom will a frequent customer state "according to IRIS" but they may state that "the EPA consensus view is…"

Interviews

Interviews were conducted with representatives of nine categories of IRIS customers. A description of each interview is presented, starting with a characterization of who was interviewed, why they were selected to be interviewed (the Hypothesis), the information collected, and an analysis of the information. Most of the interviews were supplemented with information from other customers from the user category. This information is presented as "additional information collection."

Category #1: State Agencies

Characterization: Science office providing technical support to regulatory programs

Hypothesis

State regulatory agencies use IRIS information and numerical values. It was also assumed that frequent IRIS customers are organizationally located in a science and research-related office within the agency or within the state public health department.

Information Collection

Scientists from a science and research office within a state environmental regulatory agency were interviewed. In addition, the project was described to the Environmental Council of the States (ECOS) a national non-profit, non-partisan association of state and territorial environmental agency leaders. Following the ECOS briefing, several state officials requested the opportunity to provide their views on the utility of IRIS.

The formal interview with State #1 was with scientists who have advanced degrees in toxicology and related fields. The representatives work within a research and science assistance office which provides services to various media programs, including site remediation, soil standards, and air quality permitting. The office/agency devotes more resources to risk assessment-related activities than do most state agencies. Several state agencies have established science and research offices but few are as well staffed with scientists. The staff interviewed was seasoned scientists with years of experience: “we can remember before IRIS, when there were risk assessments but nothing else.”

The representatives interviewed rely on IRIS information and numerical values, but they “have the flexibility and resources to not rely on IRIS” if they choose. Therefore they “cast a critical eye” to judge whether a file is dated and whether or not it is as data rich as other files.

They use IRIS in a variety of ways, all relating to regulatory decision making, for example, developing guidance and criteria, and making site-specific decisions. IRIS ultimately feeds into most regulatory decisions (where there is an IRIS file on the chemical of concern). IRIS is also used to answer a specific question, by a citizen for example, but IRIS is not used as a communication tool. The state drinking water act mandates that the agency must conduct its own health-based risk assessment for certain chemicals, so the office routinely conducts risk assessments. In addition, for chemicals of key concern to the state -- and there are many -- the agency calculates its own RfDs.

The agency regulatory programs occasionally express concern about the age of some IRIS files and will ask the state science and research office to complement the file with

additional data from the literature or conduct further analysis. Regulatory programs will also ask the office to evaluate data and research submitted by responsible parties, and the office relies on IRIS when addressing that type of request.

The interviewees expressed great frustration at EPA's slow pace in finalizing more IRIS files. The office, although well resourced compared to other state programs, has a significant chemical assessment work load and the absence of IRIS files makes it difficult to fulfill its obligations. The office staff believes that EPA has the capability to develop IRIS files, but for some reason the development of IRIS files has slowed significantly, leading to frustrations and ultimately affecting relations with EPA. Statements such as, "We understand that there must be reasons for the delay, but we don't care, we just want more files." "Most of us believe that the delays, which I assume are due to "getting it done right", are seldom worth the wait." "If we saw a huge improvement in the product then we could justify the wait, but that has not been the case," were expressed by the interviewees.

The state agency is more fortunate than most state agencies because it does have experience risk assessors on staff; but like any agency "we have limits, and we certainly can't do as thorough of a job as EPA can, particularly with peer review." One interviewee cited a recent situation where a responsible party asked the agency to conduct a risk assessment for a chemical for which there is no IRIS file: "we can do it but we feel resentful, and more importantly it leads to inconsistencies between states, for example, we know that California and Massachusetts are doing their risk assessments (on the chemical of concern.)" "And to make matters worse, it never ends because we continually have to spend time and money defending our work." "All our disappointments and resentment is due to high expectations; the bar was set high in IRIS' past, it has been a useful, reliable, trustful source."

The representatives wondered if there could be a way in which the work they do on a chemical may be used by IRIS: "even better, could EPA fund us to do such work? We don't think we can do things better, it's just that we have to do the risk assessments on certain chemicals, we have had no choice, and we would like to see the effort put to use."

The staff believes that ORD needs to conduct some form of customer outreach. IRIS training may be a good idea in general, however, "we are a mature staff and really don't need IRIS training." However, they wonder why ORD has not been more proactive in reaching out to customers, particularly state customers, to find out their needs.

Additional State Information Collection

State #2, which asked if they could offer their views on IRIS, has a science and research office similar to State #1. The representatives interviewed expressed thoughts similar to those of State #1.

The staff uses IRIS frequently; to find information on a chemical they are researching, and when providing support to agency regulatory programs. They use IRIS information when conducting risk assessments, and also find the "IRIS process" to be a valuable tool: "we fit IRIS data and values into our department framework." The staff accesses other sources, particularly the guidance and numerical values issued by the State of California, but "ultimately there is no comparison to IRIS, there is no other information source that is as well peer reviewed and presents an agency consensus view." They also noted that IRIS has more credibility and name recognition than any other source. The office director cited the example of a meeting she had where the department commissioner asked "did this come from IRIS?" The office director does not believe the Commissioner has ever personally used IRIS, but the Commissioner knows that IRIS is the most credible source of information.

The staff emphatically stated that the "key limitation by far with IRIS is the absence of files on certain chemicals." This limitation received a great deal of attention and consternation when the state recently had to develop a regulatory approach for perchlorate: "this has made people much more aware of the value of IRIS and the dilemma when there is not a final IRIS file." It was added that the department Commissioner was involved in the perchlorate assessment and thus is aware of how difficult it is for the department when there is no IRIS file.

The staff is concerned that some IRIS files are "dated" and there is an "incremental decrease in their value to us based on age; the older a file is the more dependent we are on other sources of information, and we look at those sources harder than we would for a more current IRIS file." However, staff still uses and relies upon old IRIS files, particularly for site specific risk assessments. The only upside to the absence of an IRIS file on a key chemical is that program offices more highly value the work of the science and research office. However, office staff would prefer that the IRIS program be strengthened and enhanced.

The staff is aware that there are reasons why the pace of issuing IRIS files has slowed, but their information source is the publication Inside EPA. Based on that source, they believe the reasons must be politically motivated. They have never requested an explanation from ORD or any other EPA office, but welcome a presentation or description of the status of the IRIS process.

The staff would welcome a forum for two-way communication with ORD; "we want EPA to understand our situation; that we can't wait on an IRIS file, that the discussions and decision process for a site is usually one year, so we have to use something to make a decisions." "Our advice is don't sacrifice the good for the perfect… also consider an interim value or allowing us access to draft files and risk assessments, any information that we could use to help us to our job in the absence of an IRIS file." Ideally they want NCEA to "share some insight with us as early as possible, where they are going with a file, not the bottom line, but just their thinking, sharing from one toxicologist to another."

State #3, is representative of a state with very limited resources to conduct risk assessments. The state environmental regulatory agency does not have a toxicologist on staff; however, an engineer, knowledgeable in the field, has compiled a state risk assessment/risk management guidance manual. The guidance manual cites IRIS as the preferred source of information.

The state regulatory programs use IRIS for information on chemicals of concern, but rely on the EPA regional office to provide risk assessment expertise. The staff does not evaluate IRIS files (date of file, adequacy of information); and it uses IRIS as if it were formal guidance: "this is a guidance tool we are using." The staff has "no problems with existing files," rather their concern is the absence of files on chemicals in which they have to make decisions.

State Public Health Agency

In state #4, a toxicologist and frequent user of IRIS working in a state public health agency was interviewed. Her office is required by state statute to provide technical assistance to the environmental regulatory agency for the purpose of setting groundwater quality standards. IRIS is always the first source of information she uses in devising numerical values. She also accesses other data bases and will review studies cited on IRIS and other sources.

She closely analyzes the IRIS files she uses to determine if information is dated or if she believes the numerical value offered is not sufficiently protective. She much prefers to rely upon an IRIS file because it "makes it harder for industry and the Department of Defense to challenge" the state standard. Thus, she will rely upon a file she believes is dated because a dated IRIS file is still more credible than any other source.

She is increasingly using European Union information sources but finds it difficult to maneuver through the sites and is uncertain who develops the information and for what purposes. She did recently use a European Union database when doing research on toluene.

Her only criticism of IRIS is the absence of files on chemicals in which she must determine a safe drinking water value. Although she "enjoys" determining a numerical value, it is time consuming to do so, plus she must continually defend the process to arrive at the value. In addition, if IRIS issues a file on the chemical subsequent to her work, she must compare the state value to IRIS and likely make changes.

She does not know for sure why there are not IRIS files on key chemicals but she suspects that it is due to interference by regulated parties.

Analysis

The state staff interviewed are frequent IRIS customers and rely on the database to make regulatory decisions. They believe IRIS is highly credible and it is almost always the source used to make regulatory decisions. They find IRIS easy to use, as well as credible, and therefore it is the first site they go to for all information relating to a specific chemical and EPA risk assessment procedures, initiatives and guidance.

IRIS has high name recognition among state regulatory decision makers, such as media program directors, commissioners and other political appointees. Thus, using an IRIS file as the scientific basis for a regulatory decision is expected and seldom challenged. Similarly, responsible parties seldom challenge an IRIS file, unless the file is severely out dated, but even then the IRIS file is the information source of choice. The only criticism of IRIS the state representatives expressed was the absence of files for key, and often controversial chemicals. Because the state risk assessment process is so dependent on IRIS, states are hugely impacted in the absence of a file.

The state representatives interviewed are only vaguely aware of the IRIS file development process, including the peer review process used and interagency reviews. They know files are peer reviewed – that is one of the reasons IRIS is so credible – but they don't know if it is the peer review process which contributes to the delay in issuing final files. In general, the state representatives have little contact with NCEA and are uncertain about the Center's IRIS related role and responsibilities. However, the state representatives would welcome the opportunity to learn more about the IRIS process and the operations of NCEA.

Category #2: Chemical Manufacturing Industry

Characterization: Company with toxicologists engaged in research as well a regulatory support.

Hypothesis

Industry – particularly the chemical manufacturing industry—is greatly impacted by IRIS files and thus routinely uses and follows the development of files.

Information Collection

Representatives from two large chemical manufacturing companies were interviewed. The representatives are toxicologists by training and have experiences in regulatory compliance as well as research. Their regulatory experiences are with US EPA headquarters and regional offices, state agencies and with other countries.

Chemical company #1 uses IRIS as a starting point in conducting its own assessment of chemicals they manufacture, leading to the preparation of numerical values. The company essentially "conducts our own IRIS like assessment" and therefore values the criteria used by ORD. Like EPA, the company has its own internal risk assessment policies and processes.

The company has global operations and uses IRIS when interacting with other country regulatory bodies: "The reason we are able to use IRIS globally is the rigorous peer review process and the fact that it presents EPA consensus views."

The absence of an IRIS file makes interactions with regulatory bodies more difficult. However, the worst-case situation is when there is a "draft risk assessment that regulators are using but there is no standard process or other way to predict the results of using the draft risk assessment." In addition, it is problematic when US state regulatory agencies, in the absence of an IRIS file, "turn to other databases, which typically leads to uncertainty."

The company monitors chemical databases and the development of numerical values. But the knowledge of, and comfort with these sources is not the same as with IRIS. For example, when addressing other sources, company representatives were uncertain of the status of databases and initiatives and thus used qualifying statements such as: "Health Canada has numerical values; I think… some states have calculated toxicity values, maybe Texas and Michigan but they are not in a database… Colorado has TCE slope factors, I believe… Kentucky was developing lead factors but backed off..."

The representatives have experiences with several EPA regional offices and they believe that "regions use IRIS differently; for example Region III uses some type of values table,

which still might be around; Regions 9 and 4 also have their own tables, all the tables have common roots in IRIS but there seems to be differences."

Company #2 always "starts with IRIS" when researching a chemical but "looks to supplement and compare IRIS with other databases, including those in Europe." The company wishes regulatory bodies did the same: "start with IRIS but consider all available information, including information we could provide."

Company #2 expressed many of the same concerns as company #1. The representatives emphasized that they have their own internal risk assessment process and therefore view IRIS files for the "thought process behind the file" as much as for the information itself: "just the other day I checked an IRIS value and how they came up with the value… it was a nice compilation, I completely understood their thinking."

Although the company always uses IRIS, it also relies upon other databases and wishes that "regulators were more open to other sources of information (other than IRIS) including information that we provide." They indicated that some states are more willing than others to supplement an IRIS file with information from other databases or that provided by the company.

The company aggressively compares and contrasts IRIS to other databases, such as IUCLID and other United Kingdom and European Union based information sources: "the UK did a better job of presenting naphthalene exposure information in its database." However, the company always starts with IRIS and IRIS is always the benchmark for comparison.

IRIS is frequently used for regulatory discussions in other counties and the company finds that reassuring: "what would be ideal is a harmonization of various databases so we could know what to expect in all cases."

Analysis

Large chemical companies typically have research or technical staff that provides several functions, including the provision of risk assessment –related assistance to others in the company who deal with regulatory concerns. Thus, industry customers use IRIS as a "chemical database" as well as a "regulatory driver." In addition, chemical companies often engage in review and comment opportunities when IRIS files are under development and going through the review process.

The chemical industry's relationship with IRIS, therefore, is complex; for example, a company which manufactures a chemical going through the IRIS review process may express strong views concerning EPA's interpretation of the peer reviewed literature. In addition, a company or coalition of companies, may suggest EPA delay issuance of an IRIS file until further research -- often funded by the industry -- is completed. However, once an IRIS file is final, companies believe they have no alternative but to accept the

IRIS file. In that regard, companies must be very familiar with relevant files and how the information and numerical values are applied in a regulatory context.

Most importantly, although a company may disagree with an IRIS file, they typically prefer having a "flawed" IRIS file rather than no IRIS file for the chemical of concern. This is because the absence of an IRIS file creates great uncertainty and can lead to protracted and uncertain discussions with multiple regulatory bodies.

The two companies interviewed cited examples of files in which they disagreed with the EPA assessment; however, both clearly stated that they value and respect IRIS. Both companies have used IRIS values in regulatory discussion overseas and both see the global benefit IRIS provides. They both expressed an interest in some degree of global harmonization of risk assessment approaches and chemical numerical values.

The industry-EPA relationship in regard to chemical risk assessment is often thought of as being contentious, and it certainly can be. However, the IRIS staff, and toxicologists and other scientists working for large chemical companies have a great deal in common. Most notably they both are charged with assessing the risks posed by chemicals and they both must develop and follow a rigorous scientific process.

The companies interviewed are familiar with other chemical and risk assessment-related databases and initiatives but are most comfortable with IRIS. Although they find value in using other databases, they do not consider the other databases to be comparable to IRIS.

Category #3: Downstream Industry User of Chemicals

Characterization: Company which proclaims to "choose" chemicals for use and considers itself environmentally aware.

Hypothesis

Companies that use, but don't produce chemicals, are IRIS customers and have different use experiences than do manufacturers. Increasingly, downstream users of chemicals and chemical products are reconsidering their purchasing process and are seeking credible information to assist them in making purchasing decisions.

Information Collection

Two toxicologists with a large chemical purchasing company were interviewed. In addition, one of the developers of the company's chemical selection criteria was also interviewed. The company prides itself on being environmentally aware and its web site proclaims that it "manufactures each of its products to strict self-imposed environmental standards. The environmental impact of all products is minimized throughout their entire life cycle, including formulation, packaging, application and disposal." To achieve its stated mission, the company has "adopted long-term worldwide environmental goals to phase out the use of some specific chemicals, to minimize waste and reduce pollution during manufacturing, to reduce packaging, and to recycle virtually all materials used in manufacturing facilities."

The representatives interviewed stated that IRIS is used by scientists within the company for many purposes, but primarily to assess the impacts of chemicals and products on human health and the environment. IRIS is typically used to research chemicals, usually for "internal" purposes rather than regulatory purposes: "we follow the regulatory values but it is not the principal reason we use IRIS. " They stated that they have used IRIS "since its inception, we like the fact that it is an EPA voice, even though the regulatory values are not the driver for us."

The company develops numerical values for internal use, such as assessing the risk posed by its own products and determining which chemicals to purchase. When developing a value the company first examines the relevant IRIS file and makes a judgment about the values included in the file: "we realize it is a hard thing to do, and generally EPA does a good job, we usually have a feeling of confidence about IRIS file."

The company also uses IRIS and other chemical databases to classify all the ingredients that go into their products according to their impact on the environment and human health.

The company representatives use other databases; for example TOMES, a commercial database which is described on the company web site as a "user-friendly, industrial chemical database providing rapid, easy access to medical and hazard information needed for safe management of chemicals in the workplace, evaluating exposures, quick response to emergency situations, and regulatory compliance." The interviewees find TOMES to be easier than IRIS for finding primary literature, but overall it is not as valuable as IRIS.

The company representatives also access European Union databases but they find it difficult to locate needed information, or determine the origin and intent of the information. They also use the California Toxicity Criteria database and the TERA (Toxicological Excellence for Risk Assessment) system but not to the degree they use IRIS.

The interviewees find IRIS to be easy to use, but believe a short introduction for new users would be useful, as well as a "Quick Card" for summary information. In addition, they would like to be able to access EPA pesticide risk assessment and related information through IRIS: "ideally, the pesticide risk assessments would be included in IRIS files."

The company scientists would like to see more IRIS files and older files updated. In the longer term, they would like to be able to access a globally harmonized risk assessment database: "IRIS but with global, not just U.S. support."

The company would welcome a dialogue with ORD NCEA and sees the value in discussing and sharing risk assessment practices. They are less certain as to whether they would be willing to share their internal derived values with EPA and other companies" "it is somewhat an ownership issue, plus we don't want them critiqued, but we would like to see what other companies have done."

Analysis

IRIS can have a significant impact on companies that are downstream users of chemicals. Increasingly, companies that use chemicals in the product manufacturing process, and retail organizations, are considering a chemical's impact on human health and the environment. In conducting such formal or even informal analyses and judgments, they rely on IRIS.

IRIS provides a benchmark for companies that develop their own numerical values. They can compare their values to an IRIS RfD, for example, however, in the absence of an IRIS file obviously there is no benchmark available for comparison.

Category #4: Federal Agency

Characterization: large department that uses chemicals to achieve its mission and is a regulated party.

Hypothesis

There are federal agencies that use chemicals for industrial operations and thus are also regulated parties. It was assumed that the department interviewed uses IRIS to research chemicals and to be aware of emerging regulatory concerns.

Information Collection

Scientists and analysts from several different offices within the department were interviewed during a two-hour conference call. Two staff participated in person and eleven others were on the phone. Most of the participants were scientists, with advanced degrees in toxicology or related fields. All the participants were frequent IRIS users.

The representatives interviewed use IRIS in a variety of ways and their experiences are slightly different, however, they all stated that they are dependent on IRIS in order to fulfill their overall mission and specific tasks. Many representatives said that they operate under written guidance mandating the use of IRIS; but they feel IRIS is a valuable and useful tool which they would use even if it was not required. There evidently is not a departmental-wide policy regarding the use of IRIS, rather individual programs have developed their own guidance and policy. For example, one office has issued a policy memo that spells out how they are to use IRIS; the process includes three steps: step 1 is to use IRIS, step 2 is to consider other peer reviewed sources, and step 3 is other sources not peer reviewed.

One of the toxicologist stated that she uses IRIS in two basic ways: applied science, which would include developing toxicological values; and for biomedical research, which includes using IRIS to find primary sources of information. Other interviewees stated they use IRIS for risk assessments in general, to support cleanup and restoration decisions, for issuing permits, and to develop their own health based exposure guidelines. Some offices within the department, such as technical service centers, have developed their own health based exposure guidelines, and IRIS was used in developing the guidelines. Other offices have relied upon IRIS in developing screening levels for surface sampling programs.

Most the interviewees feel they are able to critically review an IRIS file: “but I really don’t think we have any latitude in using or not using IRIS, we have to use it.” Another interviewee stated: “we rarely dispute IRIS, only when there is a state number which is more conservative.”

The department has operations globally and uses IRIS when assessing exposure to employees working overseas. The department also has operations in various states and has found a difference in the way different states use IRIS, particularly between California and other states.

They do not view IRIS as a communication tool: "it is hard to communicate IRIS information to the public; how to explain the imprecise nature of the information, such as the concept of spanning one order of magnitude." They also find it difficult to communicate IRIS information when they "really don't know how NCEA arrived at the finding." They face an increased challenge in California: "I have to compare California values to IRIS values and communicate that to public audiences."

Because they are so dependent on IRIS and because IRIS is operated by EPA -- a fellow federal agency -- many of the interviewees expressed the view that there should be greater coordination between the agencies; more sharing of ideas and draft information. In addition, some stated that as federal officials they should have more involvement than other customers.

Many of the interviewees must deal with chemicals for which there is no IRIS file: "that is quite often the case, the majority of the time lately; most values do not come from IRIS." The interviewees expressed frustration about having to spend the extra time and resources required in the absence of an IRIS file. Their frustration is increased by the knowledge that ORD has likely conducted a risk assessment and perhaps developed a draft IRIS file: "I understand why perhaps we shouldn't use a draft but it would be nice to have access to the information." That opinion was voiced by another interviewee who stated: "our policy is not to use draft values, but nonetheless it would be helpful to be able to access the information."

Additional Federal Agency Information Collection

Representatives from another federal agency that uses chemicals as part of its mission asked for the opportunity to express views on IRIS. In general, the views were consistent with those expressed by the representatives during the formal interview. The representatives work in the agency's Washington headquarters and their views are impacted by knowledge of interagency discussions on specific chemicals, and analyses of EPA risk assessment practices, such as the May, 2006 Government Accountability office report "Human health Risk Assessment: EPA Has Taken Steps to Strengthen Its Process, but Improvements Needed in Planning, Data Development, and Training."

The representatives offered different views regarding the use of draft risk assessment and draft IRIS files. They believe that the use of such draft materials can be harmful to the regulatory process: "We want a final file only, it hurts us when drafts are used… for example with TCE, states and even EPA Regions used draft assessments. I understand why states use a draft but shouldn't regions be more disciplined?"

The representatives also expressed concern about IRIS Track: "It is useful to tell when things have been accomplished, but it is very uneven when it comes to projecting key dates, so we don't know when to rely upon it."

Additional Information from a Federal Science Agency

Discussions were also held with a representative from another federal agency, but one which is not a regulated party. The representative is a senior scientist who heads a office of six toxicologists who use frequently use IRIS but rely more heavily on a World Health Organization process and database with which the agency is an active participant. "I use IRIS to determine hazards of the presence of contaminants in the food supply, my first source is the WHO source because we are part of it; then I go to IRIS."

His office relies upon several information sources but he has a comfort level with IRIS because "the paradigm is the same, maybe different names for the same thing, for example the NOEL, but we all look at it in the same way, we all look at the key study…sometimes EPA will apply a modifying factor which we disagree with, but essentially we are on the same page."

The representative has been in government service throughout the history of IRIS and therefore his views are based n experience and are illuminating: "our experience is that IRIS files always look reasonable; our only issue is when data is not there and EPA has to apply a default factor. I am not comfortable when default factors are applied in the absence of information when there is no underlying biologic information."

Analysis

Scientists and analysts in Federal agencies use IRIS is the same manners as do other customers: as a source of comprehensive information on a chemical; and to seek information for use for regulatory purposes. All the customers interviewed use IRIS as a principal source of information for a chemical of concern. Those who use IRIS for regulatory purposes are very dependent on the database and are challenged when there is not a file for a chemical of concern. Federal agency customers who use IRIS for general information do rely upon other databases; however, for domestic regulatory purposes they have no satisfactory alternative to IRIS. Other databases exist which can provide some assistance, but there is no substitute for an IRIS file.

What sets apart the federal agency customer from other users is the sense that they should, or at least could, have greater involvement in the IRIS file development process. Many IRIS customers are involved in the review and comment opportunity afforded by ORD during the file development process. For example, industry customers spend a great deal of time and resources conducting research and offering their views to ORD. But industry usually understands that there are limits to the extent of their involvement. However, other federal agency customers are understandably tempted to request special access for members of the "federal family." The representative from the federal science

agency best addressed the temptation to be involved when he said: “I did have one major disagreement with IRIS and it was over methyl mercury; I believed that we should have been more involved, it was not a pleasant experience; but I have gotten over it and realized that I can’t influence an IRIS file.” His recollection was not bitter; it was more of a lesson learned.

Category # 5: Trade Association

Characterization: A senior toxicologist who works for a Washington, D.C. based trade association whose members are impacted by EPA risk assessments and IRIS files.

Hypothesis

Industry trade associations, whose members are impacted by IRIS files, provide assistance to their members regarding IRIS files of concern.

Information Collection

The interviewee's title is senior director for scientific affairs. She is a toxicologist who provides technical and policy assistance to association members. The members are downstream users of chemicals and their products are not normally associated with chemicals, but are impacted significantly by IRIS files.

As a toxicologist, the interviewee knows IRIS well, but her main use of the database is to determine "do we have a problem with this chemical?" She and her members understand the necessity of IRIS in the decision making process. They know from experience that the existence of a peer reviewed, EPA consensus database makes for quicker and better informed decisions. However, because the members are not in the chemical manufacturing business they are concerned that they are not as involved and aware as they should be. The association staff and members consult other databases, but IRIS is typically the first source of information accessed.

The trade association member companies have toxicologists on staff who know about IRIS, but they typically do not follow the development of specific files. This may be because the members have come to expect the association staff to keep them informed on IRIS and other risk assessment-related concerns. The trade association has two committees in particular for which IRIS is a priority; the toxicology and risk committee and the product safety committee. However, IRIS does impact and therefore is of interest to other committees and offices including regulatory affairs, legal, government affairs and science.

The trade association is concerned about global risk assessment issues, particularly the European Union's increasing involvement. She believes that the EU is doing more and more risk assessments and developing databases and doing so without the benefit of a U.S. voice: "what is occurring now is almost the opposite of harmonization; there is a direct political component to this, the EU is promoting their approach is ways that the U.S. is not, and IRIS is a key U.S. product and needs to be promoted globally." She continued by stating: "EU is forming all these risk assessment related committees but I don't see the U.S. doing the same; thus developing countries are turning to the EU, whereas the U.S. has the best product, IRIS."

As a Washington, DC. based scientist, she has a better than average understanding of the ORD organizational structure and has been able to "track down a real person on the IRIS staff." Although she benefited from talking to the NCEA staff person she understands why it might be wise to have a separation between the file managers and the ultimate customers. But she thinks it important that the staff understand the importance of IRIS: "IRIS is a valuable, essential product and it needs to be properly maintained."

Unlike many IRIS customers, her members are not greatly impacted by the absence of a file: "we can go to another source or if necessary derive our own value." But she would like to see the IRIS Track feature become more reliable: "I need a more accurate accounting of when IRIS files will be completed; my members want to know and they turn to me."

She believes she would benefit from NCEA briefings or other dialog opportunities to achieve a better understanding of how the Agency is applying uncertainly factors and other risk assessment concepts. In addition, she would like to see increased discussion regarding the appropriate industry role in chemical specific research.

Analysis

Trade association staff play a key role in describing and explaining IRIS to members and helping them engage in and understand the process. It is in the best interest of all concerned that such staff fully understand the process and is able to effectively communicate to members. The interviewee has a better than average understanding of IRIS content and the file development process, however, there are IRIS features of which she was unaware.

The interviewee expressed concern about ORD's tendency to be produce overly protective risk assessment and numerical values. However, she also expressed interest in having the Agency more aggressively promote the use of IRIS globally. This sentiment was expressed by other industry representatives: that IRIS may have its problems but it is often better than EU risk assessment-related products.

Category #6: Research Organization

Characterization: Senior scientist working at a nonprofit, independent research organization which provides high-quality, impartial, and relevant science on the health effects of air pollution.

Hypothesis: Scientists at research organizations are frequent IRIS users.

Information Collection

The interviewee is a toxicologist, whose title is principal scientist. She is the most frequent user of IRIS within the organization; although her colleagues on staff periodically consult IRIS. She primarily uses IRIS to research a particular chemical. When conducting research she always consults IRIS but it is not usually the first database she consults unless she is seeking numerical values or other regulatory based information. She also frequently uses National Library of Medicine databases, including MEDLINE and the Hazardous Substances Data Bank.

What sets IRIS apart from other databases she uses is that IRIS presents numerical values and is used in regulatory decision making. When using IRIS she always opens up the entire file "in order to get the full benefit." However, she does not make a judgment about the quality of a file: "it is what it is, just like IARC and others."

She finds IRIS very easy to use: "there is no need for training; the site is very easy to use." IRIS is well known by her work colleagues, and the scientists who serve on the various committees the organization has established. The research organization is funded by government and a segment of the transportation industry, and both are aware of the significance of IRIS. She understands the impact IRIS has on the regulatory process: "for us IRIS is a key source of information, but it is not THE source; but I understand for state regulators it is THE source."

Her organization is not involved directly with regulatory issues, but she is impacted by the absence of an IRIS file. Although she can turn to other sources of information, she recognizes that IRIS is the most widely used and cited source: "there is no other "one" source; I will check out the California database but it is not the same, it has limitations which IRIS does not." She understands why access to a draft IRIS file can be problematic but "I can't cite a draft, but it would be nice to be aware of the information, for example we are soon publishing a formaldehyde document and I wanted the most current information, so it would have been nice to have access to the draft formaldehyde risk assessment."

Although impacted by the absence of an IRIS file, she understands why it occurs: "it is the same everywhere, IARC also takes a long time, 2-3 years following the meeting; the PAH draft for example is not out yet; it is frustrating but it is the norm."

Additional Information Collection

A discussion was held with two staff from an industry-funded research organization. Both stated that IRIS is one of several databases they use in their daily work. Typically they use IRIS to find listings of primary sources of information on a specific chemical.

Analysis

Frequent users working for research organizations are not "dependent" on IRIS and therefore are able to objectively view the utility of IRIS. Because they can use a number of different data sources to conduct their research, they provide a good test to the value of IRIS as a source of information, not as a regulatory tool.

The interviewee favorably compares IRIS to the services offered by the National Library of Medicine. Furthermore, she is not aggrieved by the absence of a chemical file; and although she would welcome more IRIS files, she understands, from experience, the inherent difficulties of arriving at scientific consensus.

Category #7: Academic Institutions

Characterization: An internationally known school of public health with a risk science and public policy institute.

Hypothesis

Environmental sciences and public health programs within academic institutions teach students about the availability of chemical and toxicological databases. It is assumed that IRIS is referenced in classroom discussions, and/or that student assignments require the use of IRIS or other chemical databases.

Information Collection

Two faculty members at a university school of public health were interviewed. Both work within a risk sciences and policy program which undertakes education, service, and research in risk policy. The program strives to provide scientists and decision makers with the tools necessary to ensure that environmental health policies result in improved public health.

The program offers "multidisciplinary education designed to broaden the base of scientific knowledge underlying risk assessment and thus bridge the gap between environmental health science and policy." The research and service activities are intended to improve the science base for risk assessment, cultivate better risk assessment methods, and enhance the risk management process.

One of the faculty members interviewed teaches an introduction to risk policy course. In his course introductory lecture, the instructor addresses risk assessment, and IRIS is described as a source of information necessary to conduct a risk assessment. The instructor also presents a lecture on scientific uncertainty where he references IRIS. Students are not required to use IRIS but often they cite IRIS in writing assignments. The instructor also gives a lecture for the environmental health sciences department on principals of risk assessment and he refers to IRIS.

The other faculty member interviewed also addresses IRIS and other databases, such as the ATSDR Tox Profiles, in classroom lectures, including her quantitative methods in risk assessment class. She noted that she and other instructors typically provide students with information necessary to complete an assignment; to ensure that all students are working from the same information. Often the information provided is from a specific IRIS chemical file. A third instructor, not interviewed, references IRIS in his dose-response class and will refer students to various web sites, but students are not required to do a web-database project.

The instructor stated that "we teach the EPA style of risk assessment and of course IRIS is essential to that process." She added that the term "IRIS" seems to stick with students: "we describe the EPA Risk Assessment Forum, and the risk assessment cancer guidelines among other services, but the students don't seem to remember those like they do IRIS."

The instructors also use IRIS for their own research and to keep informed of subject matters on which they lecture. One instructor stated "I access it myself when I am doing a community environmental health assessment, I have also used Region 6 Risk Based Concentrations." She also noted that she uses the IRIS glossary.

Analysis

IRIS is not prominently featured in classroom instruction, but it is routinely mentioned as part of the risk assessment process. The referencing of IRIS has likely contributed to the databases' high name recognition among the students. It is highly significant that the program teaches the "EPA risk assessment methodology" and that IRIS is a critical element of that approach. Thus, students are inclined to think as EPA risk assessment and IRIS as being somewhat synonymous.

Category #8: Environmental Health Non Governmental Organization

Characterization: An NGO that actively follows EPA risk assessment and IRIS issues.

Hypothesis

A national NGO recognizes the impact of IRIS and has offered views, through publications and presentations, on risk assessment issues of the importance of IRIS.

Information Collection

An interview was conducted with a senior toxicologist who works at the Washington headquarters of a NGO that focuses on environmental health concerns. The scientist believes that she is the only one in her office who could be considered a frequent IRIS user. She has written articles in which IRIS is cited and closely follows the IRIS file development process. She is familiar with other EPA programs and offices, particularly the EPA Office of Pesticides Programs, and the National Toxicology Program, and therefore she is able to compare IRIS processes and services to those programs.

IRIS is one of several databases the interviewee uses, but she believes what separates IRIS from others is how it presents numerical values and it has an extensive peer review process. She uses IRIS as a "chemicals database" when conducting research, but also relies on IRIS when following regulatory developments. In addition, she uses IRIS services, such as the Definitions: "I have it bookmarked; I use them all the time, it includes slope factor, RfD, bench mark dose; it's the only place I know where EPA offers definitions, a lot of EPA documents list acronyms but don't define the terms."

She does not use IRIS when communicating with her members and the general public. "I believe IRIS is best suited for use by toxicologists and other scientists, I usually use ATSDR Tox Facts when communicating with the public."

She would like to have opportunities to interact with IRIS staff to discuss chemicals of concern. Although more knowledgeable than most about EPA and IRIS; she is not fully aware of how IRIS is managed: "I'm not sure if there is an individual IRIS file manager. I know for the pesticide program there are file managers but they are never in the job too long and seldom can answer my questions, but it would be nice to have a point person who can refer me to the appropriate scientist." She is not looking for confidential information, rather "I want to talk scientist to scientist, I want advice, access to scientists so we can talk weight of evidence for example."

She believes that ORD needs to be issuing more files "particularly economically important chemicals; and the staff should be left alone to do that." Of all the frequent users interviewed, she expressed the most pointed views on why the pace of issuing final IRIS files has slowed. She believes that lack of adequate resources is a primary reason

for the slowing of the pace; but also feels that the Office of Management and Budget has contributed to delays.

The interviewee believes that outreach to IRIS customers is needed, would be valued, and would be mutually beneficial: "I think it would be in IRIS' best interest to reach out to customers, we could be supportive… it's a way of rallying support." She has participated in other EPA outreach initiatives, including the Office of Pesticide Programs dialogue committee which meets quarterly. She has found the group useful for "staying up to date on developments… also meeting staff and developing relationships, it makes us feel like they care; we (the stakeholders) tell them what we want on the agenda; there are disagreements but that is to be expected, I helped start a sub committee."

Analysis

NGO's do not typically have a large scientific staff, and therefore there are few frequent IRIS users. However, NGO staff recognizes the impact IRIS and thus are engaged in the IRIS process debate. The views of the interviewee are similar to those expressed by a variety of users; that ORD needs to issue more IRIS files but the files should be of high quality and should undergo thorough peer review.

The interviewee is one of the most frequent users of IRIS in the NGO community. She understands the IRIS process, appreciates side features of IRIS (definitions, links) and makes presentations which address IRIS; yet she is not fully aware of some key IRIS features and protocols. For example, she suggested that IRIS offer a list serve, similar to the one offered by the National Toxicology Program; so evidently she was not aware that IRIS does have a list serve. Similarly, she was uncertain whether there is a manager for every IRIS file under development. Perhaps she misspoke during the interview, but it is more likely that she, like many frequent users, is not aware of the full range of services offered.

Category #9: Non United States Customer

Characterization: A United Kingdom (UK) academic institution that provides occupational health services to a UK governmental agency.

Hypothesis:

IRIS is used in other countries by governmental agencies and academic institutions.

Information Collection:

A professor of environmental health, within an academic institute of environmental health was interviewed. He is a senior staff member of the institute and previously worked for the UK government. According to its web site the institute aims to promote a healthier environment through: facilitating information exchange; identifying and evaluating environment and health issues; and managing research programmes on the adverse effects of chemicals.

The institute functions as an independent organization, largely funded by UK government departments and agencies by way of specific research and consultancy contracts. The staff is primarily toxicologists and other "health" related scientists.

The interviewee primarily uses IRIS as a resource in the preparation of criteria documents on occupational exposure limits: "we use IRIS and other database as well, whatever there is, we use."

"The main way we use IRIS is as part of critical review work conducted in house. We go to IRIS because it is peer reviewed and it provides an excellent starting point to identify key primary sources but also to get a sense of the key issues; for example how numerical values were developed."

IRIS is well known within the UK chemical research and analysis community: "I sit on standard development bodies, particularly relating to occupational health, and I work with UK regulators and I know that they use IRIS." But unlike U.S. state and federal agencies, the UK regulators "don't de facto adopt IRIS numerical values."

The interviewee believes that historically IRIS has been a very valuable source but as the European Union has developed their own Directives there has been greater reliance on EU sources and Directives and less on IRIS, although IRIS remains a key influence.

He is aware that the pace of new IRIS files has also slowed down in recent years and he assumes it is due to the same problems encountered with EU Environmental Substances Regulations documents (ESRs.) "We used to rely on the ESRs, but the process was very difficult, every member state had to agree on a chemical assessment; so delays were

common and we were criticized, eventually the delays and criticism contributed to the establishment of REACH; there were too much iteration, with little significant change." He added that the EU has "only put out maybe twenty or so ESR documents over an 8-10 year period."

Although not fully aware of the IRIS file development process, he assumes that the process is somewhat similar to his EU experiences: "there is a trade-off between timeliness and quality; but the notion that you can get buy in from all stakeholders is wrong; in fact things tend to get more complicated as delays occur." He added: "I believe that changes for the sake of quality are seldom significant, if there was extremely important new information then I would recommend waiting but that is often not the case."

Analysis

The interviewee's core statement regarding IRIS is almost identical to statements made by scientists with U.S. state regulatory agencies, chemical manufacturing companies, and non-governmental organizations:

> We go to IRIS because it is peer reviewed and it provides an excellent starting point to identify key primary sources but also to get a sense of the key risk assessment practices; for example how the RfDs were developed.

Unlike most IRIS frequent users, he understands, based on experience, why there are delays in developing new files. He hopes that the process can be improved but understands the inherently difficult task of arriving at a consensus.