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4 HEARING ON ``CHEMICAL RISK ASSESSMENT: WHAT WORKS FOR JOBS
5 AND THE ECONOMY?''
6 THURSDAY, OCTOBER 6, 2011
7 House of Representatives,
8 Subcommittee on Environment and the Economy
9 Committee on Energy and Commerce
10 Washington, D.C.

11 The subcommittee met, pursuant to call, at 9:06 a.m., in
12 Room 2123 of the Rayburn House Office Building, Hon. John
13 Shimkus [Chairman of the Subcommittee] presiding.

14 Members present: Representatives Shimkus, Murphy, Pitts,
15 Bass, Harper, Cassidy, Gardner, Barton, Green, Butterfield,
16 Barrow, and DeGette.

17 Staff present: Caroline Basile, Staff Assistant; Anita
18 Bradley, Senior Policy Advisor to Chairman Emeritus; Jerry

19 Couri, Professional Staff Member, Environment; Dave McCarthy,
20 Chief Counsel, Environment/Economy; Tina Richards, Counsel,
21 Environment/Economy; Chris Sarley, Policy Coordinator,
22 Environment/Economy; Brett Scott, Staff Assistant; Lyn
23 Walker, Coordinator, Admin/Human Resources; Tom Wilbur, Staff
24 Assistant; Alex Yergin, Legislative Clerk; Jacqueline Cohen,
25 Democratic Counsel; and Billie McGrane, Democratic Assistant
26 Clerk.

|
27 Mr. {Shimkus.} The hearing will come to order. We want
28 to welcome the first and second panels and I will start with
29 my first opening statement. And I recognize myself for 5
30 minutes.

31 It has been no secret to anyone following our Committee
32 that we have been taking a very specific look at the
33 regulatory climate in this country where it is imbalanced and
34 unworkable. In doing so, I and others have been clear that
35 while we advocate the maintenance of commonsense
36 environmental and public health protections, we also need to
37 be careful about the impacts of government encroachment and
38 that these efforts not discourage job protection and economic
39 growth. Today's hearing is another step to appreciate these
40 issues.

41 To understand the final regulatory product and the
42 economic impacts of EPA activities, I think it is important
43 to appreciate the process used by the Agency to get those
44 results. Our hearing will delve into one of the foundational
45 parts of EPA's activities: the work of the Integrated Risk
46 Information System, also known as IRIS.

47 I have been a strong advocate for high-quality science
48 that is objective and valid. Moreover, I understand that
49 many are concerned about IRIS's activities on specific

50 chemicals. I am not here to defend any particular chemical.
51 This hearing is not about specific chemicals. To truly
52 protect the public from harm and negative economic outcomes,
53 we need an unbiased process informing policymakers about the
54 science, not policymakers informing the science.

55 IRIS was created over 25 years ago to provide EPA with
56 information to develop policy surrounding human health
57 effects from exposure to chemicals. There is no doubt
58 providing such high-quality science-based assessment is
59 critical to EPA's mission. The question is whether IRIS is
60 in fact fulfilling this goal or have results begun to develop
61 to support specific policy objectives?

62 From our subcommittee's perspective, we need to grasp
63 that IRIS is the program making scientific assessments about
64 chemical substances that EPA program offices use to set
65 federal limits for various environmental laws, including the
66 Safe Drinking Water Act and the Solid Waste Disposal Act. In
67 addition, many states rely on IRIS data for their own
68 environmental program purposes.

69 We are honored today to have a collection of very
70 distinguished witnesses and I appreciate the time and
71 sacrifices they have made to be with us. Among the testimony
72 we will receive is from the administration and their view of
73 IRIS and its role. I look forward to getting an update on

74 EPA's 2009 reforms to IRIS, as well as where things stand
75 with the Chapter 7, long-term recommendations of the National
76 Academies of Science for IRIS.

77 In addition, we will have insight on whether IRIS
78 assessments are doing what they should, if states are finding
79 IRIS work reliable, how much we should care about IRIS
80 assessment impacts on jobs and the economy, and is there a
81 better way for EPA to perform these assessments? These
82 recommendations could be helpful as we think about more
83 global issues affecting the EPA.

84 I hope all members will use this opportunity to
85 understand the process, discuss the integrity of the basic
86 science assessed at EPA, and appreciate how and when policy
87 considerations converge in this process and their impact on
88 jobs and the economy.

89 And I will now yield back my time and recognize the
90 ranking member, Mr. Green, for 5 minutes.

91 [The prepared statement of Mr. Shimkus follows:]

92 ***** COMMITTEE INSERT *****

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93 Mr. {Green.} Thank you, Mr. Chairman. I thank you for
94 holding this hearing today entitled ``Chemical Risk
95 Assessment: What Works for Jobs in the Economy?''

96 Risk assessment is a critical component in the
97 protection of public health and the environment. Without
98 adequate risk assessment, legislators and regulators cannot
99 make informed and wise decisions about risk management. EPA
100 has the responsibility to manage the Integrated Risk
101 Information System, or IRIS, to inform the public, industry,
102 and policymakers with the strongest and best-available
103 science on a variety of potentially hazardous materials in
104 the most non-political manner.

105 In 1985, they established IRIS to help the Agency
106 develop consensus opinions within the Agency about the health
107 effects from the chronic exposure to chemicals. Currently,
108 the EPA has assessments of 550 chemicals. These assessments
109 are utilized by the EPA to further their mission and to set
110 standards to protect human health and environment. IRIS
111 assessments can be used in regulations that garner a lot of
112 attention. In recent years, this attention has not been
113 positive.

114 In 2008, the Energy and Commerce Committee held a
115 hearing in the Oversight and Investigations Subcommittee on

116 IRIS and a GAO report that exposed concerns about the IRIS
117 program. At the hearing, the GAO testified that there was a
118 backlog of 70 chemicals in the IRIS system that needed to be
119 completed but that only four had been completed in 2008. And
120 half the 540 chemicals that were currently in IRIS possibly
121 had outdated risk assessments. On top of that, there are
122 hundreds of other chemicals that have been referred to the
123 IRIS system but have not even begun the assessment process.
124 I also note that since the hearing in 2008, IRIS has only
125 released assessments on 10 additional chemicals.

126 In that 2008 hearing, I expressed concern regarding the
127 IRIS assessment of dioxin. If you look at the dioxin section
128 on IRIS webpage, you see a timeline. It appears that IRIS
129 has been assessing dioxin since 1985. I asked questions
130 about this assessment in 2008, and now 3 years later, EPA
131 released a statement that IRIS's assessment on dioxin will be
132 finalized in 2012.

133 Dioxin is a compound that we know is very dangerous and
134 far too prevalent in and around the district I represent
135 along the Houston Ship Channel. Just outside our district,
136 we have the San Jacinto Waste Pits Superfund site which
137 consisted of submerged waste pits from an old paper mill that
138 were recently discovered to be leaching high levels of dioxin
139 in the San Jacinto River and there into the Galveston Bay.

140 Fish advisories have been extended to larger and larger
141 areas, creating a threat both to the people who fish for food
142 and for the large port fishing industry in the area.

143 Dioxin status as a toxic compound should not be
144 controversial, so the fact that it has still taken an
145 additional 3 or 4 years for IRIS to complete its risk
146 assessment is very discouraging. If the EPA wants IRIS's
147 assessments to be viewed as legitimately scientific and
148 reliable, they must take steps to streamline their reviewing
149 process to issue assessments in a timely manner so they are
150 not outdated or make the assessments clearer and easier to
151 understand.

152 The National Academy of Sciences issued guidance on how
153 to improve IRIS assessments, and I hope the EPA witness can
154 update the committee on the improvements being made in the
155 IRIS program and what they intend to do in the future to
156 correct the problems within the program. We need to restore
157 the public confidence in EPA's risk assessment and chemical
158 regulatory system and the first step must be to ensure the
159 integrity of EPA's scientific information and practices.

160 I look forward to hearing the testimony of all of our
161 witnesses, but particularly Dr. Honeycutt from TCEQ who is
162 from my home State of Texas and we work with them
163 particularly on that dioxin facility in the San Jacinto area.

164 And Mr. Chairman, I yield back my time.

165 [The prepared statement of Mr. Green follows:]

166 ***** COMMITTEE INSERT *****

|
167 Mr. {Shimkus.} The gentleman yields back his time.

168 Does the gentleman from Mississippi seek time for an
169 opening statement? Gentleman from Louisiana? Having no
170 other members present to seek time, I would like to welcome
171 the first panel.

172 First of all, let me introduce the entire panel, and
173 then we will go 5-minute opening statements.

174 First we have Dr. Paul Anastas, the Assistant
175 Administrator to the Office of Research and Development in
176 the United States Environmental Protection Agency. Sir,
177 welcome. Also, Mr. David Trimble, Director of the Natural
178 Resources and Environment for the U.S. Government
179 Accountability Office; and Mr. David C. Dorman, Dean for
180 Research and Graduate Studies at North Carolina State
181 University on behalf of the National Academy of Sciences.

182 We have two great panels and we again welcome you. And
183 I would like to first turn to Dr. Anastas from the EPA for a
184 5-minute opening statement. We have got a lot of members.
185 We have got time if you go over. That is not a problem. If
186 it goes too far, then it might be a problem.

187 So welcome and you are recognized, sir.

|
188 ^STATEMENTS OF PAUL ANASTAS, ASSISTANT ADMINISTRATOR, OFFICE
189 OF RESEARCH AND DEVELOPMENT, U.S. ENVIRONMENTAL PROTECTION
190 AGENCY; DAVID C. TRIMBLE, DIRECTOR, NATURAL RESOURCES AND
191 ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE; AND DAVID
192 C. DORMAN, DEAN FOR RESEARCH AND GRADUATE STUDIES, NORTH
193 CAROLINA UNIVERSITY, ON BEHALF OF NATIONAL ACADEMY OF
194 SCIENCES

|
195 ^STATEMENT OF PAUL ANASTAS

196 } Mr. {Anastas.} Good morning, Chairman Shimkus, Ranking
197 Member Greene and other members of the Committee. My name is
198 Paul Anastas and I am the assistant administrator for the
199 Office of Research and Development at the Environmental
200 Protection Agency and the Agency's science advisor. Thank
201 you for the opportunity to be with you here this morning to
202 discuss the Integrated Risk Information System, also known as
203 IRIS.

204 At the EPA, we firmly believe that the American people
205 deserve the best possible scientific information about the
206 chemicals that they may encounter in their air, water, and
207 land. When those chemicals may potentially affect their
208 health, their children, and the health of their communities,

209 we have the duty to vigorously study them and share what we
210 know with our citizens.

211 Every day, expert scientists in EPA's IRIS program work
212 to fulfill that duty providing this information by drawing
213 upon the best science both from the Agency as well as from
214 universities and research institutes around the world. The
215 assessments that we develop as part of the IRIS program are
216 scientific documents, not regulations. This is an important
217 distinction. While the information they contain is useful in
218 our agency decisions, it is also widely used by communities,
219 businesses, environmental groups, and public citizens. For
220 those reasons and more, we recognize the importance of
221 maintaining the highest level of scientific integrity when
222 generating these IRIS assessments. That is why every draft
223 IRIS assessment is made available to the public, to our
224 sister federal agencies, and to the broader scientific
225 community for their review and comment.

226 The draft assessments we produce undergo one of the most
227 rigorous, independent peer review processes in any scientific
228 field. This peer review process makes our IRIS assessments
229 stronger. The comments that we receive are valued and
230 addressed. This is precisely why we undergo such rigorous
231 review. This is how the scientific process works.

232 We also recognized that continuous improvement is what

233 science is all about. That is why in May 2009, Administrator
234 Jackson put into place a strengthened and streamlined IRIS
235 process. This new process not only strengthened the
236 scientific integrity of the IRIS program, it also shortened
237 the average time frame for generation of IRIS assessments
238 from 5 years to just 23 months. Since 2009, EPA has
239 completed 20 IRIS assessments, twice as many assessments as
240 were finalized in the previous 4 years combined.

241 But our efforts to continuously improve didn't stop
242 there. This past July, I announced a plan to further
243 strengthen the IRIS program. Because our assessments are
244 widely used in the decisions of state and local governments,
245 businesses, and American citizens, we have focused on making
246 them clearer, more concise, and ensuring that our methods and
247 scientific assumptions are more transparent to the users.
248 These improvements, which we began aggressively implementing
249 in July, directly address the suggestions from the National
250 Academy of Sciences and other independent experts. The NAS
251 made six major suggestions to improve the generation of IRIS
252 documents, and we are implementing all of those
253 recommendations. Those recommendations and how we are
254 dealing with them are detailed in my written testimony, and I
255 will be happy to expand on those.

256 We will pursue continuous improvement, but we will

257 proceed in a way that does not slow or prevent our ability to
258 provide the best scientific information to the public. That
259 is what the American people expect and deserve. We recognize
260 that the only reason to deeply understand a problem is to
261 inform and empower its solution. When we look at the
262 information that is being transmitted through our IRIS
263 assessments, information about what makes a chemical
264 hazardous, that information can be used to design the next
265 generation of chemicals so that they are not hazardous in the
266 first place. We believe this information empowers innovation
267 in the marketplace.

268 Leading companies understand this potential for
269 innovation and are pursuing it aggressively through the use
270 of green chemistry. Green chemistry is the design of
271 chemical products and processes that reduce or eliminate the
272 use and generation of hazardous substances. By understanding
273 the properties that make a chemical hazardous, scientists and
274 industry and in academia are meeting environmental and
275 economical simultaneously through the principles of green
276 chemistry design.

277 New life-saving medicines are being developed in ways
278 that produce dramatically less waste through green chemistry.
279 New high-performing materials are being invented to serve
280 their purpose and then degrade harmlessly into the

281 environment through green chemistry design. New products are
282 being introduced into the marketplace that are safe for
283 children and attractive to consumers through green chemistry.
284 All of this progress is being made in sectors ranging from
285 agriculture to energy, transportation to telecommunications,
286 and cosmetics to computing. Companies across the American
287 economy are increasing profits and enhancing competitiveness
288 through green chemistry. That is the power and the potential
289 of green chemistry. And that is why the lessons we learn
290 from toxicology and the IRIS program are important for
291 feeding innovation.

292 In conclusion, whether it is through IRIS or our other
293 cutting-edge scientific research, EPA is providing critical
294 information to companies, entrepreneurs, and researchers so
295 they can make new discoveries and develop new innovations all
296 while protecting health and the environment. That is the
297 real power of understanding chemical hazard and that is why
298 EPA's IRIS program is so critically important.

299 We will continue to improve this program using the best
300 science not only to understand the problems of today, but to
301 inform and empower the solutions of tomorrow. It is what is
302 necessary for the environment, for public health, for the
303 economy, and I think we can all agree that it is what the
304 American people deserve.

305 Thank you for the opportunity to speak here this
306 morning. I will be happy to answer any questions as is
307 appropriate.

308 [The prepared statement of Mr. Anastas follows:]

309 ***** INSERT 1 *****

|

310 Mr. {Shimkus.} Thank you, Dr. Anastas.

311 And we would now like to recognize Mr. David Trimble.

312 Sir, you are recognized for 5 minutes likewise. Take your

313 time and get through it and we welcome you here.

|
314 ^STATEMENT OF DAVID C. TRIMBLE

315 } Mr. {Trimble.} Chairman Shimkus, Ranking Member Green,
316 and members of the subcommittee, I am pleased to be here
317 today to discuss our prior work and recommendations on EPA's
318 Integrated Risk Information System.

319 As you know, the IRIS database contains EPA's scientific
320 position on the potential human health effects of exposure to
321 more than 550 chemicals in the environment. IRIS assessments
322 are a critical component of the EPA's capacity to support
323 scientifically sound risk management decisions, policies, and
324 regulations.

325 In March 2008, we reported that the IRIS program was at
326 serious risk of becoming obsolete because the Agency has not
327 been able to complete timely credible chemical assessments or
328 decrease its backlog of 70 ongoing assessments. We found
329 that the time frames for completing assessments were
330 unacceptably long, often taking over a decade. In many
331 cases, assessments became obsolete before they could be
332 finalized and were stuck in an endless loop of assessment and
333 reassessment.

334 In April of 2008, EPA revised the IRIS process, but the
335 changes made were not responsive to our recommendations. The

336 new process was actually worse than the one it replaced,
337 institutionalizing process that resulted in frequent delays
338 by enabling OMB to determine when an IRIS assessment could
339 move forward. Further, this process effectively excluded the
340 content of OMB's comments to EPA and those from other
341 interested federal agencies from the public record.

342 Concerned with these programs and the Agency's lack of
343 responsiveness, we added EPA's process for assessing and
344 controlling toxic chemicals to our January 2009 report on
345 government-wide high-risk areas in need of an increased
346 attention by executive agencies and Congress. In May 2009,
347 EPA had made significant changes to the IRIS process. In
348 June of that year, we testified that these changes, if
349 implemented and managed effectively, would be largely
350 responsive to the recommendations we made in our March 2008
351 report. Let me highlight three of these key changes.

352 First, the IRIS process would be managed by EPA rather
353 than OMB as the former process was, restoring independence to
354 EPA. Second, it required that all written comments provided
355 by OMB and other federal agencies and draft IRIS assessments
356 be part of the public record, adding transparency and
357 credibility to the process. Third, the procedures
358 consolidated and eliminated steps, streamlining the process.

359 Notably, the new process eliminated the step under which

360 other federal agencies could have IRIS assessments suspended
361 indefinitely to conduct additional research. As we have
362 reported, we understand that there may be exceptional
363 circumstances under which it may be appropriate to wait for
364 the results of an important ongoing study. However, as a
365 general rule, we believe that the IRIS assessments that are
366 based on the best available science is a standard that would
367 best support the goal of completing assessments within
368 reasonable time periods and minimizing the need to conduct
369 wasteful rework.

370 While the May 2009 IRIS process changes reflect a
371 significant improvement that can help EPA restore the
372 integrity and productivity of the IRIS program, EPA still
373 faces significant management challenges as it seeks to
374 completely timely, credible IRIS assessments.

375 First, EPA must continue to balance the need for using
376 the best available science with completing IRIS assessments
377 in a timely manner. As we have reported, even 1 delay can
378 have a domino effect requiring the process to essentially be
379 repeated to incorporate changing science.

380 Second, EPA faces long-standing difficulties in
381 completing assessments of chemicals of key concern, those
382 that are both widespread and likely to cause significant
383 health issues. We believe that EPA must continue to focus on

384 the best available science, obtaining credible expert review,
385 and finalizing IRIS assessments.

386 Third, EPA must be disciplined in keeping the timelines
387 even in the absence of fixed statutory deadlines for
388 completing IRIS assessments.

389 Lastly, we believe that to produce timely credible IRIS
390 assessments over a sustained period of time, it will be
391 important for EPA to maintain a consistent process going
392 forward.

393 We are currently reviewing EPA's implementation of its
394 revised 2009 IRIS assessment process and its response to our
395 previous recommendations. As part of this review, we will be
396 examining EPA's response to NAS's recommendations for
397 improvements to the IRIS process. We plan to issue this
398 report later this year.

399 That concludes the summary of my statement. I will be
400 happy to answer any questions any member of this committee
401 may have.

402 [The prepared statement of Mr. Trimble follows:]

403 ***** INSERT 2 *****

|
404 Mr. {Shimkus.} Thank you very much.

405 Now, I would like to recognize for 5 minutes Dr. David
406 Dorman, who is testifying on behalf of the National Academy
407 of Sciences. Sir, welcome. You have 5 minutes, and take
408 your time on the opening statement.

|
409 ^STATEMENT OF DAVID C. DORMAN

410 } Mr. {Dorman.} Thank you. Good morning, Mr. Chairman
411 and members of the subcommittee. My name is David Dorman. I
412 am a professor of toxicology at North Carolina State
413 University and I served on the National Research Council's
414 Committee to Review EPA's Draft IRIS Assessment of
415 Formaldehyde.

416 The NRC report was developed by 15 scientists drawn by
417 academia, federal laboratories, state government, and other
418 organizations. The scientists that served on the NRC
419 committee were selected by the National Academies and had a
420 wide array of scientific expertise related to this effort.
421 As part of the Academy's process, a draft of the committee's
422 report was subjected to extensive peer review prior to
423 release by the NRC.

424 It is important to note that the NRC was not asked to
425 conduct an independent assessment of formaldehyde but rather
426 we were charged with examining EPA's identification of
427 potential cancer and non-cancer health effects, the
428 toxicological basis for those health effects, and the way
429 uncertainty factors used to derive the reference
430 concentrations and the quantified cancer unit risk estimates

431 for formaldehyde. The major findings of our NRC committee
432 were as follows:

433 First, we found that the U.S. EPA was faced with the
434 daunting task of compiling a complex and large toxicological
435 database for formaldehyde. For the most part, the committee
436 agreed that EPA achieved this goal. The EPA's draft
437 assessment for formaldehyde was prepared using the Agency's
438 current format and approach for IRIS documents. Our
439 committee found the EPA's document to be quite cumbersome and
440 was too often lacking in clarity and transparency. We were
441 troubled that previous NRC committees reviewing similar
442 assessments for other chemicals had identified similar
443 deficiencies.

444 Third, our committee therefore offered a set of
445 suggestions for changes in the IRIS development process that
446 might help EPA improve its approach. In essence, we provided
447 EPA with a roadmap for changes in the development process.
448 The term roadmap was used because the topics that needed to
449 be addressed were set out, but detailed guidance was not
450 provided by the committee since that was seen as beyond our
451 committee's charge.

452 Thus, the committee provided general guidance for the
453 overall process and some specific guidance on the specific
454 tests and steps of evidence identification, evidence review

455 and evaluation, weight-of-evidence evaluation, selection of
456 studies for derivation and calculation of reference
457 concentrations and unit risk. For each of these steps, there
458 are underlying processes that would need to be examined and
459 reconsidered. The NRC report provides further details on
460 these recommendations.

461 Finally, the committee recognized that any revision of
462 the approach would involve an extensive effort by EPA staff
463 and others, and consequently, it did not recommend that EPA
464 delay the revision of the formaldehyde assessment while
465 revisions of the IRIS approach were undertaken. In fact, we
466 provided specific guidance as to the steps needed to revise
467 the existing draft IRIS assessment. Models for conducting
468 IRIS assessments more effectively and efficiently are
469 available, and the committee provided several examples in the
470 present report. Thus, EPA might be able to make changes in
471 its process relatively quickly by selecting and adapting
472 existing approaches as it moves towards a more state-of-art
473 process.

474 As a member of the committee, I have been pleased to
475 hear that Dr. Anastas and other EPA administrators plan on
476 implementing suggestions found in the NRC formaldehyde
477 report.

478 In closing, I would like to thank all of you for

479 inviting me here to discuss the NRC's report and I welcome
480 your questions.

481 [The prepared statement of Mr. Dorman follows:]

482 ***** INSERT 3 *****

|
483 Mr. {Shimkus.} Thank you very much. And we will start.

484 And I will recognize myself for 5 minutes for the first
485 round of questions.

486 First to Dr. Anastas, you have been clear in the past
487 that IRIS does not perform risk assessments; rather this is
488 done by risk managers in the program office, and I have been
489 trying to handle those differences. EPA's website, though,
490 states that IRIS is ``a human health assessment program that
491 evaluates quantitative and qualitative risk information on
492 effects that may result from exposure to specific chemical
493 substances found in the environment. If this is true, how
494 can IRIS not be doing ``risk assessments'' if it has to
495 distill qualitative risk information and quantitative risk
496 information?

497 Mr. {Anastas.} The elements of a full risk assessment
498 have been outlined in a landmark 1983 NAS report that looks
499 at risk identification and characterization, dose response as
500 well as exposure. What an IRIS assessment is today is
501 looking at the hazard identification and characterization and
502 the dose response. Until that information--which is powerful
503 and actually fundamental to a risk assessment--is combined
504 with the exposure models and the exposures that are expected
505 and anticipated under a regulatory program or some other

506 scenario, that is when it becomes a full risk assessment and
507 is used in risk management. This is the important but only
508 the front-end part of that overall calculus.

509 Mr. {Shimkus.} Thank you. You did answer this question
510 in your opening statement. I am just going to go through
511 three quick ones. You stated in your opening statement that
512 the IRIS office evaluates peer review recommendations,
513 correct? Is that what you said in your opening statement?

514 Mr. {Anastas.} Right. When we get any peer review
515 comments, we always review them and address them, yes.

516 Mr. {Shimkus.} Do you write draft assessments and
517 evaluate public comments?

518 Mr. {Anastas.} We submit our draft assessments for
519 public comment and the public and the scientific community
520 comments on those drafts.

521 Mr. {Shimkus.} Does your office decide what to include
522 and exclude and what other changes to be made to its own work
523 based upon those two responses?

524 Mr. {Anastas.} Through an extensive and iterative
525 process, we receive those comments, address those comments,
526 and transparently show how we have addressed those comments.

527 Mr. {Shimkus.} Thank you.

528 Mr. Trimble, what effect does IRIS risk values have on
529 the regulated community or the private marketplace?

530 Mr. {Trimble.} Well, as Dr. Anastas has indicated, it
531 forms the basis for many of EPA's regulatory decisions. For
532 example, in drinking water standards, the information in IRIS
533 will be married up with occurrence data whether or not the
534 contaminant has been found in water across the country to
535 inform decisions about whether or not, for example, to
536 regulate a contaminant. So it is the building block for many
537 of EPA's regulatory decisions.

538 Mr. {Shimkus.} But if the IRIS assessment is not
539 finalized for over a period, then what is that effect?

540 Mr. {Trimble.} Then basically everything comes to a
541 screeching halt because the mission teams like the water
542 office or air, they don't have sort of the basic science they
543 need to carry out their mission.

544 Mr. {Shimkus.} And then the private sector who might be
545 preparing for this are--

546 Mr. {Trimble.} Everyone is left hanging.

547 Mr. {Shimkus.} Thank you. And Dr. Dorman, I have
548 talked about this numerous times in my years here on the
549 committee. What is the value of a risk assessment value that
550 identifies a level below a natural occurring background
551 level?

552 Mr. {Dorman.} So that is a dilemma for a number of
553 chemicals that exist endogenously, and my own opinion--and I

554 think it also was echoed in a report--is that for
555 formaldehyde in particular, those endogenous levels need to
556 inform the assessment as performed by EPA or other agencies.
557 On a personal note, kind of speaking not for the committee, I
558 think that becomes a challenge and I think that oftentimes we
559 don't regulate chemicals, we don't consider the risk
560 assessment in light of that endogenous background.

561 Mr. {Shimkus.} And endogenous meaning?

562 Mr. {Dorman.} That is what is present normally in the
563 body just from consumption of food or for metabolism. It is
564 basically what your body produces.

565 Mr. {Shimkus.} So in the numerous years I have been on
566 this committee and dealing with--you know, we have water
567 issues that would have endogenous elements in it, we have
568 ground that has endogenous elements, so I guess for the
569 layman, having a standard that is lower than naturally
570 occurring, cleaning the soil up and then you can't replace it
571 with the same soil. This same soil is still higher than the
572 standard established by this risk assessment, is that
573 correct?

574 Mr. {Dorman.} Correct. That could be the case.

575 Mr. {Shimkus.} Thank you very much.

576 Now, I would like to recognize my colleague, Mr. Green,
577 for 5 minutes.

578 Mr. {Green.} Thank you, Mr. Chairman.

579 And I guess why IRIS is so important--and I happen to
580 represent the largest petrochemical complex in the country--
581 is that all the chemicals used properly are something that we
582 really benefit from, but that is why IRIS is so important
583 because of those beneficiary uses, but in certain levels.
584 And the best example is formaldehyde and dioxin. We need
585 those but when used properly and that is why IRIS is so
586 important to do.

587 Mr. Administrator, I mentioned in my opening statement I
588 was concerned with the length of time it has taken IRIS to
589 complete assessment of dioxin due to the presence of dioxin
590 super flight in our district. It is my understanding that
591 IRIS is expected to release a portion of the final dioxin
592 assessment in January of 2012. Is that correct? And can you
593 elaborate very briefly on why this is a two-part assessment?
594 Yes, sir.

595 Mr. {Anastas.} One of the things that I did try to
596 emphasize is that when we receive comments on an assessment,
597 we take them extremely seriously and we want to fully address
598 all of these comments. We follow the science. The science
599 is what dictates when we can release a final assessment. We
600 submitted the dioxin assessment most recently the received
601 comments on both the cancer portion of the dioxin assessment

602 and the non-cancer portion of the assessment. It is clear
603 that the comments on the non-cancer portion of the assessment
604 are things that can be readily dealt with, addressed, and
605 that we can move quickly ahead.

606 The complexity of the dioxin cancer portion of the
607 assessment are far more complex and will not be completed on
608 the same time frame as the non-cancer portion of the
609 assessment. And that is based on the science and the
610 complexity of the science and the scientific issues.

611 Mr. {Green.} This is not the first hearing that our
612 committee has had on IRIS and it is an important program that
613 has been subject to review by the GAO and the National
614 Academy of Sciences Committee for years. It has been
615 targeted because of lengthy delays and because sometimes the
616 politicalization--surprise, surprise--in Washington what
617 should be scientific process. We saw this during the Bush
618 Administration when the OMB took over management of the IRIS
619 program and the pace of the assessments slowed to a crawl.
620 The Government Accountability evaluated the peer review
621 process in 2004 and raised certain concerns.

622 Mr. Trimble, can you briefly explain the concern GAO had
623 with IRIS review system that was in place from 2004 to 2008?
624 And again I am trying to remember. Obviously, OMB reviews
625 all regulations from agencies, but this is the first time I

626 had seen that OMB would actually control the process between
627 agencies for input. So I appreciate, you know, you answering
628 that.

629 Mr. {Trimble.} Briefly, what we found at the time was
630 we had concerns regarding productivity with the IRIS program,
631 which we have talked about. At that time one of the things
632 that we noted in our reports was that OMB had involved itself
633 and taken control of 2 key steps within the process so that
634 reports and IRIS assessments could now move forward without
635 OMB's concurrence. And that was I believe when reports were
636 being sent out for review and when they were being finalized.

637 So there was one aspect that dealt with productivity and
638 EPA's independent ability to control the process, but the
639 other aspect that we reported on that was troubling was that
640 OMB's involvement and comments were non-transparent so there
641 was a lack of transparency in the public regarding what
642 changes were being made and what those comments were. OMB
643 brought in other federal agencies and also those comments
644 were not transparent being deemed by OMB at the time as
645 deliberative in nature. And so it was those two factors that
646 we reported on at the time.

647 Mr. {Green.} And again that is a different system than
648 I think we are used to, and there are times that as Members
649 if we lose at the Agency, whether the EPA or somewhere else,

650 we will go to OMB and talk about the economic impacts. And
651 that is what OMB should be doing--

652 Mr. {Trimble.} Um-hum.

653 Mr. {Green.} --and not getting involved in the actual
654 scientific assessment.

655 Dr. Dorman, I know you briefly described some of the
656 recommendations that National Science made. Can you talk
657 about particularly with the issue of formaldehyde?

658 Mr. {Dorman.} So I think in the case of formaldehyde,
659 we found largely that we had a number of areas in which we
660 agreed fully with the recommendations or the conclusions that
661 the EPA had in the IRIS document. We did have some areas in
662 which we differed as far as our interpretation of the EPA
663 document in light of the scientific evidence that is
664 available. We did give the Agency some specific
665 recommendations regarding not relying on certain studies. We
666 felt they weren't the best studies available for certain
667 endpoints like sensory irritation and others but hopefully
668 that addresses your concern.

669 Mr. {Green.} Okay, thank you. Thank you, panel.

670 Mr. {Shimkus.} The gentleman's time has expired.

671 The chair now recognizes the chairman emeritus, Mr.
672 Barton, for 5 minutes.

673 Mr. {Barton.} Thank you, Chairman Shimkus.

674 Let me ask Dr. Anastas. Are you career or you a
675 political appointee?

676 Mr. {Anastas.} I am a political appointee.

677 Mr. {Barton.} Okay. And you have been in your position
678 since the Obama Administration took office?

679 Mr. {Anastas.} Shortly thereafter. Actually, it was
680 January--

681 Mr. {Barton.} Okay.

682 Mr. {Anastas.} --of 2010.

683 Mr. {Barton.} Very good. I am going to ask you a
684 little bit different series of question in the hearing
685 because my interest, while I share some of the interest on
686 chemical issues, I am very involved in the air quality issue.

687 Does your office do any of the studies that relate to
688 ozone?

689 Mr. {Anastas.} We produce integrated scientific
690 assessments on a wide range of national ambient air quality
691 standards, including ozone.

692 Mr. {Barton.} Okay. And mercury?

693 Mr. {Anastas.} Yes, all of those substances under the
694 program.

695 Mr. {Barton.} And PM_{2.5}?

696 Mr. {Anastas.} Correct.

697 Mr. {Barton.} Okay. Is there any other office within

698 EPA that does studies on those similar to your office?

699 Mr. {Anastas.} We work closely with our Office of Air
700 and Radiation and while we do the underlying scientific
701 assessments of the kind that we are discussing in IRIS and
702 integrated scientific assessments, the Office of Air and
703 Radiation takes those basic scientific documents into their
704 regulatory process.

705 Mr. {Barton.} When the administrator is looking at
706 tightening the standards on the various criteria of
707 pollutants under the Clean Air Act, who make the decision
708 whether the study to look at the health effects is going to
709 be done internally by your office or externally?

710 Mr. {Anastas.} The process of generating a scientific
711 assessment on these chemicals would take place internally,
712 relying on a wide range of external studies--universities,
713 research institutes--and those assessments are conducted
714 internally and then put out for peer review.

715 Mr. {Barton.} Would there ever be an instance where
716 your office did not do an internal study, even if the
717 decision was made to do an external study?

718 Mr. {Anastas.} I am not familiar with a case where it
719 would be conducted completely externally. We rely on a wide
720 range of external studies to inform our assessments, but the
721 assessments that are fed into the regulatory process are

722 constructed internally.

723 Mr. {Barton.} Is it your decision whether to do the
724 external study or the administrator's decision or the deputy
725 administrator's decision or kind of a collective all of the
726 above?

727 Mr. {Anastas.} The conduct of the studies are dictated
728 by the needs of our regulatory and program offices and they
729 work closely with the Office of Research and Development to
730 identify which studies are necessary to inform their
731 regulatory actions and then we proceed. So that is the
732 process that is used.

733 Mr. {Barton.} I don't necessarily understand that
734 answer, but I don't have but a minute and a half. So can you
735 give me a definition that is generally accepted of what a
736 premature death is?

737 Mr. {Anastas.} One would look at statistically a life
738 expectancy using epidemiological models and the absence of a
739 particular effect if you are looking at, for instance, a
740 respiratory--

741 Mr. {Barton.} Well, give me a layman's definition. I
742 mean my friends on the Democratic side, when we debate these
743 environmental bills where we are attempting to delay some of
744 the EPA regulation, they trot out these studies, and they are
745 usually 10 to 15 years old, they are usually external, and

746 they all seem to predict 30,000 premature deaths a year, but
747 we have never gotten a definition of what a premature death
748 is.

749 Mr. {Anastas.} A premature death would be something
750 that shortens the otherwise--

751 Mr. {Barton.} I want to know what the definition is.
752 Is a premature death somebody who has a life expectancy of 80
753 who dies at 40 because of exposure to ozone, dies at 50, dies
754 at 35? I mean there should be some standard definition.
755 Apparently, there is not. Premature death is in the eyes of
756 the beholder.

757 Mr. {Anastas.} Their life expectancy would be shortened
758 from what it would otherwise be. So it is not set at a
759 cutoff point of how much shorter. That is--

760 Mr. {Barton.} Could you provide for the record a
761 written answer to what a premature death is?

762 Mr. {Anastas.} I would be happy to.

763 Mr. {Barton.} Whatever the definition is that your
764 agency uses, I would like to have it in writing.

765 Mr. {Anastas.} Certainly.

766 Mr. {Barton.} Thank you, sir.

767 Thank you, Mr. Chairman.

768 Mr. {Shimkus.} The chair now recognizes the gentleman
769 from Mississippi, Mr. Harper, for 5 minutes.

770 Mr. {Harper.} Thank you, Mr. Chair.

771 Dr. Anastas, just a question. Who selects who does the
772 peer review? Who is invited to join in that? Is that open?
773 Tell me how that works.

774 Mr. {Anastas.} Certainly. The peer reviews can be
775 done, for instance, by the National Academy of Sciences.
776 They can be conducted by our Science Advisory Board. They
777 can be conducted by panels of scientific experts. In the
778 case of the National Academies, they are selected certainly
779 by the Academy. The Science Advisory Board assembled ad hoc
780 panels for those reviews, and each of these types of
781 processes is a vetting for balancing different scientific
782 expertise and ensuring that there aren't ethical or conflicts
783 of interest.

784 Mr. {Harper.} When a draft is prepared and done, if
785 there is conflicting opinions by the peer review, how is that
786 dealt with? Does that appear in your draft assessment that
787 there are conflicting reports?

788 Mr. {Anastas.} The results of conflicting opinions are
789 resolved within the peer review committee themselves. They
790 can represent the different perspectives in their peer review
791 report and we would receive that report.

792 Mr. {Harper.} So is the public ever made aware that
793 there may have been a difference of opinion before that came

794 to you?

795 Mr. {Anastas.} Thank you. What is a very important
796 point that I should have emphasized is that these peer review
797 panels are publicly held. We receive public comment. The
798 peer reviews are publicly available so actually one of the
799 things that was emphasized by GAO is the necessary
800 transparency, and that is something that is very transparent
801 in this process is the peer review.

802 Mr. {Harper.} When the peer review is being completed,
803 once a final assessment is done, is that final assessment on
804 track to be reevaluated? Is it a perpetual continuous
805 reevaluation? Or something new comes in, is that subject to
806 being changed?

807 Mr. {Anastas.} There are over 500 assessments on the
808 IRIS database currently, and one of the ongoing processes
809 where we seek public input, we receive input from our various
810 program offices and regional offices is input on what should
811 be in the pipeline for highest priority either due to
812 knowledge of additional scientific information that requires
813 updating or a need to address actions that need to be taken.
814 So that is how we inform how things get updated in what
815 order. As was referenced earlier, this is an ongoing
816 challenge and why it is so important that we have increased
817 the pace of these assessments.

818 Mr. {Harper.} Can you give me the difference between
819 chemistry and green chemistry?

820 Mr. {Anastas.} Certainly. Chemistry is the study of
821 all matter and material and its transformations and green
822 chemistry is looking at how you manipulate the molecules, how
823 you build them from the atoms up so that they have a reduced
824 ability to cause toxicity to humans or the environment. In
825 the same way that we can design a substance to be green or
826 blue, flexible or brittle, we can design it so that it is
827 either capable of causing harm or far less capable of causing
828 harm.

829 Mr. {Harper.} Well, when I went to college, you could
830 major in biology or chemistry. Do you anticipate that we
831 will see green chemistry majors in our universities?

832 Mr. {Anastas.} As a matter of fact, there are Ph.D.
833 programs in major universities both in the United States and
834 elsewhere in green chemistry. There are degree programs in
835 everywhere from the U.S., India, China, Australia, and the
836 U.K.

837 Mr. {Harper.} If I have time, I would like to ask Dr.
838 Trimble a question if I may. And I am going to reach a quick
839 peer review committee. This was the NRC formaldehyde
840 committee review just a quote here.

841 It says, ``the committee is concerned about the

842 persistence of problems encountered with IRIS assessments
843 over the years and the draft was not prepared in a consistent
844 fashion. It lacks clear links to an underlying conceptual
845 framework and it does not contain sufficient documentation on
846 methods and criteria for identifying evidence from
847 epidemiologic and experimental studies, for critically
848 evaluating individual studies, for assessing the weight of
849 evidence, and for selecting studies for derivation of the
850 RFCs and unit risk assessments.''

851 Tell me your opinion on that, what that statement was.

852 Mr. {Trimble.} This may be better directed to NAS since
853 GAO has not looked or assessed the NAS's study.

854 Mr. {Harper.} Well, certainly defer then.

855 Mr. {Dorman.} Yes, sir. So what we mean by that is
856 that oftentimes when one is trying to put together a
857 database, when you are basically doing literature reviews,
858 before you begin that process, you start to lay out a
859 framework by which you are going to evaluate the literature.
860 And so as you are starting to go looking at literature, you
861 will find, per se, a chemical like formaldehyde there is
862 literally thousands of articles available in the published
863 literature on a chemical where if you search the database
864 using a word like formaldehyde you will find. And so one
865 needs to have a process by which you start to kind of weed

866 that evidence down to a sub-selection of studies and then
867 eventually key studies that you start to use in your
868 assessment, and we just felt that EPA was not transparent in
869 defining that process by which they would both identify what
870 literature you were finding and then either accept or not
871 accept certain studies and bring them forward in their
872 assessment.

873 Mr. {Harper.} I realize I am out of time and if I may,
874 Dr. Trimble, what I was wanting to ask was this: the
875 conclusions in that formaldehyde review committee seemed to
876 indicate that the same problems that were noted by GAO in '06
877 are still evidence in IRIS and I just want to know if you
878 agree or disagree?

879 Mr. {Trimble.} I will probably punt on this. This is
880 going to be part of our ongoing review, which we will be
881 reporting on in the next couple of months looking at how the
882 process has gone since then and part of that review will be
883 looking at the NAS.

884 Mr. {Harper.} That was a very polite way of not--

885 Mr. {Trimble.} Yeah, I apologize.

886 Mr. {Harper.} Thank you.

887 Mr. {Shimkus.} The gentleman yields back his time.

888 The chair now recognizes the gentleman from North
889 Carolina, Mr. Butterfield, for 5 minutes.

890 Mr. {Butterfield.} Let me thank you, Mr. Chairman, for
891 convening this very important hearing today and particularly
892 we thank the witnesses for their testimony.

893 Mr. Chairman, IRIS, as we all know, is the foundation of
894 our public health and environmental policy and it should be
895 reviewed periodically to ensure it is being carried out at
896 peak performance. And so the witnesses' testimony today has
897 been very helpful on this subject.

898 I believe to properly evaluate IRIS's performance, we
899 must have absolute clarity on the function of IRIS. Dr.
900 Anastas, let me start with you. Does IRIS make risk
901 assessments?

902 Mr. {Anastas.} No, what IRIS does is provide important
903 scientific information that gives insight on the hazards of
904 chemicals and potential health consequences of various
905 chemicals, but in order to have it be a full risk assessment,
906 it needs to have the exposure component. So while this
907 information is fundamental and essential, it is not a full
908 and complete risk assessment.

909 Mr. {Butterfield.} So do you only make hazard
910 assessments or do you do both?

911 Mr. {Anastas.} The risk assessments are done as part of
912 the regulatory process in our regulatory office.

913 Mr. {Butterfield.} But don't you agree that this is a

914 very important distinction between these two?

915 Mr. {Anastas.} It is a tremendously important
916 distinction, one that is often confused. Many people do view
917 IRIS members as regulations, as risk assessments, and it is
918 an important distinction that this is looking at just this
919 element of the scientific information.

920 Mr. {Butterfield.} That is very helpful.

921 Now, does IRIS make EPA regulations? I think we know
922 the answer but I want you to go on the record and say that.

923 Mr. {Anastas.} Well, we know how important IRIS values
924 are to regulations. They are not regulations and they are
925 not making regulations.

926 Mr. {Butterfield.} So could we say, then, that the
927 primary work of IRIS is to evaluate and integrate existing
928 scientific literature into assessments of potential hazard
929 which are then used by EPA program offices and others to
930 gauge risk and eventually set thresholds for exposure in
931 programs? Is that correct?

932 Mr. {Anastas.} That is correct.

933 Mr. {Butterfield.} In a little while, Dr. Anastas, we
934 are going to hear from Dr. Honeycutt of the Texas Commission
935 on Environmental Quality. He will claim that the EPA's most
936 recent assessment on formaldehyde calls into question the
937 safety of its hailing. Dr. Honeycutt will state that using

938 EPA's most recent assessment, formaldehyde in your breath
939 that results from normal body functions would be five times
940 higher than the highest level of EPA would call safe. Was
941 the IRIS assessment asserting that this room is now unsafe
942 due to all of the formaldehyde producers currently being
943 breathed at this time? How would you respond to this
944 assertion and what are the implications?

945 Mr. {Anastas.} Well, the IRIS assessment was not
946 concluding or implying that this room is unsafe because of
947 the air that we exhale. The formaldehyde assessment
948 benefitted greatly from the comments that were supplied by
949 the National Academies and the comments that the National
950 Academies provided are being addressed to strengthen that
951 assessment. But no, the answer is no, the assessment did not
952 imply that we are at risk because of the air that we are
953 breathing in this room.

954 Mr. {Butterfield.} Yes. Thank you very much.

955 Thank you, Mr. Chairman. I yield back.

956 Mr. {Shimkus.} I thank my colleague. I would just
957 note, Dr. Anastas, in your response you said ``not
958 concluding,'' brings up my question about are you doing a
959 risk assessment? So that is the part of this whole debate
960 that we are looking into.

961 The chair now recognizes the gentleman from

962 Pennsylvania, Mr. Pitts, for 5 minutes.

963 Mr. {Pitts.} Thank you, Mr. Chairman.

964 Dr. Anastas, is the source of a study's funding an
965 automatic disqualifier of the contents or quality of the
966 research no matter how well characterized or high quality
967 such a study is?

968 Mr. {Anastas.} The evaluation of a study is based on
969 the scientific integrity of the study. So the short answer
970 to your question is no. The importance of the rigor of the
971 study, the way that the study is conducted are the important
972 determining factors. With regard to such things as the peer
973 review and peer review panelists, ethical and conflict of
974 interest are considered at that point, for instance, for peer
975 reviewers, but in the conduct of the study, it is the
976 scientific rigor of the study.

977 Mr. {Pitts.} Other than industry funded, please tell
978 the committee what other types of funding exist for high-
979 quality scientific work?

980 Mr. {Anastas.} I think there is extensive funding for
981 high-quality research provided by the Federal Government.
982 There is certainly a wide range of our scientific agencies
983 provide funding to researchers to conduct on a wide range of
984 topics including toxicology, epidemiology, and these are
985 important sources of funding. Whether it is the National

986 Science Foundation, the National Institutes of Health, and of
987 course the Environmental Protection Agency.

988 Mr. {Pitts.} Has the EPA ever contracted with the
989 private sector or intentionally obtained scientific research
990 that was paid for by a private interest?

991 Mr. {Anastas.} I want to make sure that I give you an
992 accurate answer so I don't want to be definitive without
993 checking all of the facts. What I will pledge to do is get
994 back with you with a clear answer on that question.

995 Mr. {Pitts.} All right. To what extent does IRIS rely
996 on the scientific pronouncements made by other federal
997 agencies or coordinate with them on their activities like NTP
998 or ATSDR?

999 Mr. {Anastas.} One of the things that we ensure doing
1000 is coordinate what assessments will be done so that we
1001 certainly wouldn't want to be duplicative or overlapping or
1002 redundant. We coordinate with sister agencies not only which
1003 assessments to do to make sure that we are complementary
1004 wherever appropriate but also coordinate in our interagency
1005 reviews. Interagency reviews are transparent and inclusive
1006 and we rely heavily on the scientific expertise on our sister
1007 scientific agencies and health agencies, as well as others.

1008 Mr. {Pitts.} Thank you.

1009 Dr. Dorman, in your opinion, has EPA's IRIS process

1010 evolved to reflect improvements in the field of risk
1011 assessment?

1012 Mr. {Dorman.} So speaking for myself and not as a
1013 member of the panel, I think that approaches have been kind
1014 of mixed. In some areas, IRIS has been more considerate of
1015 modeling efforts and things like that which reflect more
1016 state-of-the-art. I think there are other areas in which the
1017 IRIS assessment program probably lags a little bit behind.
1018 But I think that IRIS does try to keep up and I think the EPA
1019 should be, you know, recognized for trying to keep up with
1020 the science as it is evolving.

1021 Mr. {Pitts.} Are you familiar with other branches of
1022 the Federal Government that are engaged in risk assessment,
1023 and if so, do those offices employ best practices that could
1024 be applied here?

1025 Mr. {Dorman.} I serve and do an advisory role on
1026 different aspects for the Federal Government, and I think
1027 there are some examples of best practices. Speaking on
1028 behalf of the committee, we did identify some of those best
1029 practices that we thought could serve a template for the
1030 Agency as they move forward on looking at revising the IRIS
1031 program.

1032 Mr. {Pitts.} How important is it for the American
1033 public that the integrated risk assessment process results in

1034 a reasonably correct assessment and what are the practical
1035 consequences of an overly precautionary assessment? What are
1036 the practical consequences of an assessment that does not
1037 identify risk?

1038 Mr. {Dorman.} Again, I think as Dr. Anastas pointed out
1039 the IRIS program is not doing the risk assessment per se;
1040 they are trying to compile the data regarding hazard
1041 identification, but I think that is extremely critical for
1042 folks. And I think it is not only an issue of an economic
1043 issue, but it is also a public health issue where the public
1044 doesn't become alarmed over health effects that may or may
1045 not be present with a certain chemical. And I think that is
1046 another area that, you know, the EPA IRIS documents do try to
1047 identify hazard identification and I think it is very
1048 critical for the public that it is done in the right way.

1049 Mr. {Pitts.} Thank you, Mr. Chairman.

1050 Mr. {Shimkus.} The gentleman's time has expired.

1051 The chair recognizes that we have been joined by my
1052 colleague from Georgia, which I think he will--

1053 Mr. {Barrow.} I thank the chairman. I will waive.

1054 Mr. {Shimkus.} He waives. The chair now recognizes the
1055 vice chairman of the subcommittee, Mr. Murphy, for 5 minutes.

1056 Mr. {Murphy.} Thank you, Mr. Chairman.

1057 Dr. Anastas, the EPA has a draft of the IRIS toxicology

1058 report for hexavalent chromium, is that correct?

1059 Mr. {Anastas.} Correct.

1060 Mr. {Murphy.} Are you aware that on May 12, 2011, a
1061 panel of independent chromium experts had significant
1062 concerns with that draft?

1063 Mr. {Anastas.} I am aware of that peer review.

1064 Mr. {Murphy.} And is the EPA prepared to incorporate
1065 more up-to-date scientific research in that based upon the
1066 information that came from the peer review and other input?

1067 Mr. {Anastas.} We are evaluating that peer review. We
1068 are evaluating the comments and concerns. While no decisions
1069 have been made, it is the practice that I have stated and I
1070 appreciate the opportunity to emphasize that we consider and
1071 we address the concerns raised in peer review.

1072 Mr. {Murphy.} Is there anything you recall in that peer
1073 review study that sticks out that says there is something
1074 that raises concerns of a particularly salient nature for
1075 you?

1076 Mr. {Anastas.} I think that this peer review has raised
1077 a number of questions about the science that is currently
1078 being conducted and the potential value of that science
1079 informing the assessment upon its completion.

1080 Mr. {Murphy.} Are you aware also of the NTP study, the
1081 doses given to test animals, that something like 5,000 parts

1082 per billion but the national drinking water standard for
1083 total chromium is 100 parts per million, and drinking water
1084 monitoring indicates that hexavalent chromium in drinking
1085 water is only about 1 to 4 parts per billion? I mean these
1086 seem to be pretty radical differences in terms of information
1087 that has come out on hexavalent chromium research versus what
1088 is really out there. How do you evaluate that sort of
1089 information when you see studies looking at some extremely
1090 high levels and then related to what is really out there?

1091 Mr. {Anastas.} It is certainly I will say a traditional
1092 methodology when studying the toxicity of a particular
1093 chemical that you want to be able to get up to the level
1094 where you see a particular toxic effect, and sometimes these
1095 levels that are required are fairly high as you mentioned.
1096 And then there is the necessary extrapolation. So this is
1097 not necessarily unusual for studies of this type.

1098 Mr. {Murphy.} But you are also drawing conclusions
1099 based upon having toxic levels can give us some
1100 misinformation. For example, a person can reach a toxic
1101 level of ingestion of H₂O, but that doesn't mean we draw
1102 conclusions based upon that. And I just want to make sure
1103 that we are also looking at these levels. I mean what is the
1104 real risk? Because none of us want to misdiagnose and then
1105 mistreat the problem.

1106 Mr. {Anastas.} This is the basis of dose response--

1107 Mr. {Murphy.} Um-hum.

1108 Mr. {Anastas.} --and getting these dose response
1109 curves, the ability to determine at which dose an effect may
1110 take place or a no-effect level is the basis of dose
1111 response, and so this is something that I know that Dr.
1112 Dorman teaches in his classes all the time in North Carolina.

1113 Mr. {Murphy.} I also heard our EPA administrator talk
1114 about dose response curves and we should look at that.

1115 Now, the Natural Resources Defense Council I believe
1116 suggested that chromium alloys pollute our soil and water
1117 supplies, but I want to make something clear. Isn't it true
1118 that there is no association between the use of chromium
1119 alloys in stainless steel in any pollution or illness? Am I
1120 correct in that?

1121 Mr. {Anastas.} What we are looking at in the IRIS
1122 assessments is the toxicity and the one we are discussing is
1123 the toxicity of chromium-6 and different matrices you can
1124 expect different considerations, and that is part of the risk
1125 assessment/risk management calculation.

1126 Mr. {Murphy.} Okay. Is that chromium-6 something that
1127 is used in stainless steel?

1128 Mr. {Anastas.} I believe chromium-6 is used in
1129 stainless steel.

1130 Mr. {Murphy.} When it is used in stainless steel, I
1131 mean stainless steel is also seen as containers for clean
1132 drinking water, surgical equipment, et cetera. Is that an
1133 issue that that chromium is actually leaching out of that
1134 stainless steel and contaminating those things?

1135 Mr. {Anastas.} Nothing in the IRIS assessment addresses
1136 any of those risk scenarios.

1137 Mr. {Murphy.} But you can look at things outside of the
1138 IRIS assessment? Here is my concern: if we are saying that
1139 that is a toxic chemical but it is used in containers which
1140 are used to have non-toxic water and sterile equipment, is it
1141 correct, then, in saying that that chromium is actually
1142 leaching out and causing problems?

1143 Mr. {Anastas.} You are identifying extremely important
1144 risk management decisions and exposure factors. Those are
1145 exactly the type of questions that are--

1146 Mr. {Murphy.} You are not giving me an answer. You are
1147 just saying it is important. I need to know--

1148 Mr. {Anastas.} What I am saying is that nothing in this
1149 health assessment would address those questions.

1150 Mr. {Murphy.} I still don't have an answer but I
1151 realize my time is up. Thank you, Mr. Chairman.

1152 Mr. {Shimkus.} Thank you. And at this time I recognize
1153 my friend from Colorado, Ms. DeGette, for 5 minutes.

1154 Ms. {DeGette.} Thank you very much, Mr. Chairman.

1155 Dr. Anastas, I want to ask you a couple of things I read
1156 in your written testimony. One is about this rider that was
1157 attached to the interior EPA appropriations bill this summer
1158 that would have delayed all IRIS assessments until the NAS
1159 recommendations were adopted and would have required NAS
1160 review of additional draft assessments. Does the
1161 administration support that policy?

1162 Mr. {Anastas.} What I can say is that the effect of
1163 those letters would be significant. I believe that Mr.
1164 Trimble did mention the concern I think that we all share of
1165 making sure that assessments come out in a timely way. The
1166 result of these riders would be significant delay of perhaps
1167 as much as a year or 2 years, and an important factor to
1168 consider is during that delay, would the assessments that are
1169 in development be brought out of date? So the impacts of
1170 this would be significant and cascading throughout not only
1171 the development of the assessments themselves but the use of
1172 these assessments.

1173 Ms. {DeGette.} What types of significant and cascading
1174 developments would there be?

1175 Mr. {Anastas.} As was mentioned earlier, these
1176 assessments are important as a foundation for different
1177 decisions and actions not only in the Agency but by States

1178 and municipalities and industry. Would these assessments
1179 then be able to inform regulatory decisions or other
1180 decisions? The answer of course is no because they would be
1181 delayed by these actions.

1182 Ms. {DeGette.} Do you think there would be an effect on
1183 public health or the environment by these delays?

1184 Mr. {Anastas.} I certainly believe that our regulatory
1185 decisions, the decisions at the state and local level and
1186 decisions made by companies and individuals impact human
1187 health and the environment, and so yes, if--

1188 Ms. {DeGette.} Okay. Your answer is yes.

1189 Mr. {Anastas.} My answer is yes.

1190 Ms. {DeGette.} Thank you. Now, thinking about it from
1191 the other side of the issue, the chemical industry and
1192 economy in general, if we had uncertainty in these standards,
1193 would that potentially also be harmful to them since they
1194 wouldn't know what was coming down the pike?

1195 Mr. {Anastas.} I think the lack of knowledge is always
1196 difficult and something to try to avoid, which is why we try
1197 to get this information out.

1198 Ms. {DeGette.} Mr. Trimble, GAO has raised concerns
1199 about the delays in the IRIS process, and you talked about
1200 that earlier and what that would mean for the credibility of
1201 assessments. Would suspending all assessments and all

1202 actions on past assessments impact the utility and
1203 credibility of the program?

1204 Mr. {Trimble.} I think as Dr. Anastas indicated, the
1205 impact would be felt most immediately by the program offices
1206 at EPA, as well as the States and others that rely on that to
1207 make regulatory decisions.

1208 Ms. {DeGette.} So there would be a lack of certainty?

1209 Mr. {Trimble.} Yeah, certainly there would be a lack of
1210 certainty and predictability. Certainly.

1211 Ms. {DeGette.} Now, in your testimony you talk about
1212 the compounding effects of delays on assessments and Dr.
1213 Anastas referred to that. Can you please explain what you
1214 mean by that?

1215 Mr. {Trimble.} Yeah, what we have reported on in the
1216 past is that when studies in the past have been suspended or
1217 delayed, what happens is that science keeps marching so that
1218 when you start to restart that study, a lot of the work has
1219 to be redone because there is new scientific literature. We
1220 have talked about evolving scientific methods, for example,
1221 you know, quantifying risk and things like that. All of
1222 those, the state-of-the-art practices change over time, so
1223 when you stop and delay, you have to catch up to what is now
1224 cutting-edge science to move forward and that causes delays.

1225 Ms. {DeGette.} In your testimony you mention that IRIS

1226 processor forms are not established in regulation or statute.
1227 Do you have any ideas for this committee about what we can do
1228 about that that you would like to share with us?

1229 Mr. {Trimble.} Well, with that I would politely demur
1230 on this.

1231 Ms. {DeGette.} I thought you might.

1232 Mr. {Trimble.} We have a report that is coming out by
1233 the end of this year looking at the implementation of the
1234 IRIS programs since the 2009 changes, so we will be reporting
1235 on that shortly.

1236 Ms. {DeGette.} Mr. Chairman, we will all look forward
1237 to getting a copy of that report. And I yield back.

1238 Mr. {Shimkus.} The gentlelady yields back her time.

1239 I ask unanimous consent for Mr. Murphy to do a unanimous
1240 consent request.

1241 Mr. {Murphy.} Mr. Chairman, I just ask this letter from
1242 the Specialty Steel industry of North America be submitted
1243 for the record in which it states, ``no hexavalent chromium
1244 is present in steel alloys.''

1245 Mr. {Shimkus.} That has been shared with the minority?
1246 Is there objection? Hearing no objection, so ordered.

1247 [The information follows:]

1248 ***** COMMITTEE INSERT *****

|
1249 Mr. {Shimkus.} The chair now recognizes the gentleman
1250 from New Hampshire for 5 minutes, Mr. Bass.

1251 Mr. {Bass.} Thank you very much, Mr. Chairman.

1252 I want to thank you all for your time and interest in
1253 being here today.

1254 Dr. Anastas, OMB guidance defines ``highly influential
1255 scientific assessment is a scientific assessment that could
1256 have a potential impact of more than \$500 million in any year
1257 on either the public or private sector or is a novel,
1258 controversial, or precedent setting or has significant
1259 interagency interest.'' Because the estimates support the
1260 Agency's regulatory activities, including costly cleanups,
1261 are the IRIS assessments routinely recognized as highly
1262 influential scientific assessments subject to the information
1263 quality and peer review guidelines?

1264 Mr. {Anastas.} I think the important discussion that we
1265 have been having has shown that these assessments are
1266 scientific inputs into regulatory decisions. They are not
1267 regulations; they are not regulatory conclusions. The
1268 considerations for economic impact are important and
1269 essential and a serious part of the deliberations that the
1270 Agency has, but these assessments are not regulations and
1271 should not be viewed as such.

1272 Mr. {Bass.} Well, I guess then in making the
1273 determination whether an IRIS assessment is highly
1274 influential, how does the EPA determine whether more than
1275 \$500 million worth of future impacts are likely?

1276 Mr. {Anastas.} The results of regulatory decisions
1277 undertake extensive cost-benefit and regulatory impact
1278 analyses. Perhaps the most important point that I could make
1279 on this is that while we are, through these assessments,
1280 identifying the hazard profile of these substances, in the
1281 absence of exposure, there is no risk. If there is no
1282 exposure, there is no risk and so there would be no reason
1283 for its management. And so while these are important inputs,
1284 it would be wrong to assume that because something has a
1285 particular hazard profile it is necessarily going to trigger
1286 a regulatory action.

1287 Mr. {Bass.} Is it possible that any IRIS assessment
1288 could later be incorporated in a regulation that has impacts
1289 of more than \$500 million?

1290 Mr. {Anastas.} Yes.

1291 Mr. {Bass.} Okay. All right. I am all set, Mr.
1292 Chairman. Thank you.

1293 Mr. {Shimkus.} The gentleman yields back his time.

1294 The chair now recognizes the gentleman from Louisiana,
1295 Mr. Cassidy, for 5 minutes.

1296 Dr. {Cassidy.} Mr. Anastas, you mention going back to
1297 Mr. Barton's questions regarding how you define premature.
1298 Let us take a person with emphysema. We know that person
1299 with emphysema is more likely to have complications from an
1300 inhaled toxin, pick ozone, so if the person with emphysema
1301 dies at 74 because of a bronchospastic asthmatic event
1302 triggered by ozone, is he compared to the average age someone
1303 dies, say 82 for a man, or is he compared to the average age
1304 that somebody with emphysema dies?

1305 Mr. {Anastas.} So when we are looking at statistical
1306 population distributions, that distribution is going to have
1307 various susceptibilities--people who are particularly
1308 susceptible--

1309 Dr. {Cassidy.} Correct.

1310 Mr. {Anastas.} --and people who are particularly
1311 resilient. So what we are talking about is average lifespan
1312 and how different effects would affect a--

1313 Dr. {Cassidy.} Correct.

1314 Mr. {Anastas.} --population. So I would not draw that
1315 conclusion based on an individual because I believe that that
1316 would not be a statistically robust approach.

1317 Dr. {Cassidy.} Wait, you don't adjust for co-
1318 morbidities when determining whether somebody dies
1319 prematurely because of exposure to a toxin?

1320 Mr. {Anastas.} No, I am saying that certainly
1321 susceptible populations do reside within that overall
1322 population--

1323 Dr. {Cassidy.} But I think--

1324 Mr. {Anastas.} --but I am saying that I wouldn't apply
1325 it to an individual.

1326 Dr. {Cassidy.} I can tell you that that would be
1327 counter to what you would do--I am a doctor. That is what
1328 you would do in medicine. You would account for co-
1329 morbidities knowing that co-morbidities have a huge influence
1330 upon the body's reaction to an external event.

1331 Mr. {Anastas.} And I absolutely agree that in dealing
1332 with an individual you absolutely need to factor in the
1333 individual's susceptibility.

1334 Dr. {Cassidy.} But I gather that you are not comparing
1335 them--

1336 Mr. {Anastas.} That would be the logical calculation.

1337 Dr. {Cassidy.} But I actually think that you actually
1338 could find--go to the VA database, for example--find the
1339 average lifespan for somebody with a certain level of
1340 pulmonary impairment and you would find, yes, for this degree
1341 of impairment they die and this degree they die at this age.
1342 But I gather that is not necessarily done?

1343 Mr. {Anastas.} I am saying that in many of the

1344 epidemiological studies that are relevant to the discussion
1345 that we were having about decreased lifespan, that that has
1346 not been the basis of those types--

1347 Dr. {Cassidy.} Okay. I got my answer. And I didn't
1348 mean to be rude. I don't mean to be curt. I apologize.

1349 Dr. Dorman, did you participate in the critique of this
1350 report, the IRIS report for formaldehyde?

1351 Mr. {Dorman.} Yes, sir.

1352 Dr. {Cassidy.} Now, I am struck because I just kind of
1353 quickly eyeball it. I am quickly eyeballing it so it may
1354 come in totally wrong. Join my wife on most occasions.

1355 If the lack of knowledge is a bad thing,
1356 misinterpretation of knowledge is even worse. As I look at
1357 the summary of your report, you say that ``the committee
1358 concludes the weight of evidence suggests formaldehyde
1359 unlikely to appear in blood as an attack molecule.'' You go
1360 on to say that, you know, kind of absorbed, quickly
1361 metabolized, it goes away, unlikely to have a systemic
1362 effect. That is kind of the, you know, as I scan what I am
1363 getting. So even though this is 1,000 pages--I looked it up--
1364 -it is 1,043-page report talking about all the things it will
1365 do to rat urine and, you know, to human nasal mucosa, really
1366 all that strongly suggests there is pertinent physical
1367 effects, and yet your report finds that that may be

1368 overstated. Is that a fair statement?

1369 Mr. {Dorman.} So I think it is a fair statement that
1370 the Academy concluded that the current best evidence
1371 indicates that formaldehyde does not reach the systemic
1372 circulation in an appreciable way. And so what we did
1373 recognize as well, though, is that formaldehyde might have
1374 certain health effects that may not require it being
1375 delivered systemically. And so, for example, if we have say
1376 rhinitis or an irritation in the nose, you might also have
1377 headache. Even though that chemical never got to the brain,
1378 that would be an example say of a stress that might be
1379 associated with that inflammation in the nose.

1380 Where we differed from the conclusions probably related
1381 most to the motive action that EPA was considering for the
1382 leukemogenic responses that have been associated with
1383 formaldehyde exposure where we felt that the weight of
1384 evidence didn't strongly support their conclusions.

1385 Dr. {Cassidy.} Yes, I am kind of struck that there is
1386 1,043 pages of stuff which documents and if you just read it,
1387 you think oh my gosh, isn't this terrible? Then I read your
1388 report and when you actually analyze it and put it in
1389 context, it isn't quite so frightening. Worrisome, but not
1390 quite that 1,043 pages of we have got to regulate. I agree
1391 with that.

1392 I also say, as a physician, it seems kind of routine. I
1393 am not sure why it has taken you so long to implement these
1394 suggestions I put forth because frankly, as a physician, if
1395 there is not rigor of methodology being explained, then the
1396 paper would never be published in a peer reviewed journal.
1397 That seems to be kind of a standard sort of scientific method
1398 of presentation.

1399 Mr. {Anastas.} If I could just mention that this is a
1400 draft assessment. We put out draft assessments for the
1401 purpose of getting this kind of critique so that we improve
1402 it for the final assessment. This is what we do. This is
1403 why we seek it out.

1404 Dr. {Cassidy.} Can I have just a minute more?

1405 Mr. {Shimkus.} Without objection, gentleman is
1406 recognized for another minute and a half.

1407 Dr. {Cassidy.} Okay. Thank you.

1408 Going back to green chemistry, it seems to me as if that
1409 would be the basis for a proposal regarding inherently safer
1410 technology.

1411 Mr. {Anastas.} Correct.

1412 Dr. {Cassidy.} Now, that actually seems you move beyond
1413 I think Mr. Butterfield suggested your role as analytic--and
1414 I will maybe paraphrase--analytic not prescriptive, but that
1415 is a little disingenuous if you are saying listen, we are

1416 going to make a value judgment as to whether or not this has
1417 a toxic effect and this does not. And frankly, there will be
1418 assumptions that credible scientists may disagree with your
1419 assumptions, and yet your findings are going to be the basis,
1420 I bet you, for regulation promoting inherently safer
1421 technology. How would you disagree with that?

1422 Mr. {Anastas.} What I tried to emphasize in my
1423 statement was when the information that we generate gives us
1424 insights not only that an individual substance may or may not
1425 be toxic and in what ways but how it is toxic, that gives us
1426 insights into the design--

1427 Dr. {Cassidy.} But you are making an assumption of
1428 toxicity that again scientists in a peer reviewed journal
1429 would disagree with your assumption, but yet your assumptions
1430 are going to guide this green chemistry which is going to
1431 guide an IST regulation.

1432 Mr. {Anastas.} With all due respect, what I am saying
1433 is not on the level of toxicity but the mechanisms by which
1434 it has any kind of biological effect. This informs the
1435 design of the molecular structures of future chemicals so
1436 that we can minimize the possibility, the probability--

1437 Dr. {Cassidy.} Give me a specific because right now
1438 that sounds very nice, but as I try and think of the
1439 particular, it seems you can't divorce yourself from

1440 assumptions of the toxicity and we already see credible
1441 dispute with your assumptions of toxicity.

1442 Mr. {Anastas.} When I am looking at a molecular
1443 structure, I know that whether or not a substance has the
1444 ability to even cause any type of toxic effect--

1445 Dr. {Cassidy.} But water can drown. Do you see what I
1446 am saying? Water has a toxic effect if you put your head
1447 underneath it for too long. And so you are right, there has
1448 to be a dose effect, and there has to be a certain substrate
1449 in which it interacts. How do you account for that?

1450 Mr. {Anastas.} If a substance cannot be inhaled, if a
1451 substance cannot be respired, ingested across biological
1452 membranes, those are all based on its physical/chemical
1453 properties. What chemists do is develop structures to
1454 control their physical/chemical properties. You can design a
1455 substance to have those physical/chemical properties so as to
1456 reduce the probability that it can cause hazardous adverse
1457 consequences.

1458 Dr. {Cassidy.} I still can't--so formaldehyde--

1459 Mr. {Shimkus.} The gentleman's time has expired.

1460 Dr. {Cassidy.} Thank you. I yield back.

1461 Mr. {Shimkus.} There are too many doctors in this room.
1462 The IQ has gone up and I can't even understand the English
1463 being spoken here sometimes. I ask unanimous consent. My

1464 colleague Mr. Green wanted to make a statement before we
1465 adjourn this panel.

1466 Mr. {Green.} Mr. Chairman, I know we have votes going
1467 to be scheduled and I think we have exhausted our questions
1468 of the panel. I want to thank the panel. I know, Doctor,
1469 you had to change your plans to be here but when I referred
1470 to the dioxin facility in our district--actually in Ted Poe's
1471 district--but EPA worked in both administrations, both in '08
1472 and '09, what I consider bureaucratic light speed to get that
1473 site on there, and we actually have it encapsulated now. And
1474 the next panel we have our Texas Commission on Environmental
1475 Quality. They actually are the ones that did the research to
1476 trace where all this dioxin would be coming from in the San
1477 Jacinto River, so that is a great example. Most people get
1478 mad at EPA. Here in Texas, you all don't think we do
1479 anything for the environment, but we do. Thank you.

1480 Mr. {Shimkus.} And the chair now also wants to ask
1481 unanimous consent that the letter dated October 4 from the
1482 American Chemistry Council be submitted for the record. That
1483 has been shared with the minority. Without objection, so
1484 ordered.

1485 [The information follows:]

1486 ***** COMMITTEE INSERT *****

|
1487 Mr. {Shimkus.} I too want to thank the first panel and
1488 for the second panel we will convene you after votes and they
1489 should be calling them any minute. So that really is not
1490 productive for us to start. And we will reconvene after
1491 votes. So with that, I will recess this hearing.

1492 [Recess.]

1493 Mr. {Shimkus.} We can get through the next panel and
1494 also get in between votes on the floor of the House, but I
1495 think we have got plenty of time, but we do want to get
1496 started.

1497 We want to welcome you. Thank you for your patience. I
1498 will do as I did with the first panel I am going to introduce
1499 you all across the board, and then we will recognize you
1500 individually for your 5-minute opening statements. Because
1501 of the time that we have, you know, I won't hold you strictly
1502 to the 5 minutes, so take your time. Make sure what you want
1503 to present is not rushed.

1504 So on this second panel, we again appreciate you all for
1505 being here. We have Dr. Michael Honeycutt, Director of
1506 Toxicology Division, Texas Council on Environmental Quality.
1507 We also have Dr. Harvey Clewell, the Hamner Institutes for
1508 Health Sciences. We have also have Mr. Jerry A. Cook,
1509 Technical Director, Chemical Products Corporation. It is

1510 good to see a mister and not all doctors. And then finally
1511 Dr. Thomas A. Burke, Associate Dean for Public Health
1512 Practice and Training, Department of Health Policy and
1513 Management at Johns Hopkins Bloomberg School of Public
1514 Health.

1515 Gentlemen, thank you for joining us, and I would like to
1516 recognize Dr. Honeycutt for 5 minutes for his opening
1517 statement.

|
1518 ^STATEMENTS OF MICHAEL HONEYCUTT, DIRECTOR OF TOXICOLOGY
1519 DIVISION, TEXAS COUNCIL ON ENVIRONMENTAL QUALITY; HARVEY
1520 CLEWELL, THE HAMNER INSTITUTES FOR HEALTH SCIENCES; JERRY A.
1521 COOK, TECHNICAL DIRECTOR, CHEMICAL PRODUCTS CORPORATION; AND
1522 THOMAS A. BURKE, ASSOCIATE DEAN FOR PUBLIC HEALTH PRACTICE
1523 AND TRAINING, DEPARTMENT OF HEALTH POLICY AND MANAGEMENT, THE
1524 JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

|
1525 ^STATEMENT OF MICHAEL HONEYCUTT

1526 } Mr. {Honeycutt.} Good morning, Mr. Chairman and members
1527 of the committee. My name is Michael Honeycutt. I am
1528 director of the Toxicology Division at the Texas Commission
1529 on Environmental Quality. I would like to touch briefly on
1530 Texas' perspective on the science that EPA is using or not
1531 using for chemical risk assessments in recent years and the
1532 implications for regulatory agencies and the public.

1533 I have been a toxicologist and a risk assessor for Texas
1534 for over 15 years. In past years, we have had disagreements
1535 with EPA, but they have not really been based on science
1536 issues so much as on policy issues. An example of this would
1537 be that EPA does not want to consider TCEQ rules, which in
1538 many cases are more stringent than their cleanup values when

1539 addressing a cleanup site in Texas. However, we have always
1540 been able to work out our differences amicably.

1541 In recent years, though, EPA chemical risk assessments
1542 have become more precautionary in nature instead of relying
1543 on scientific data. The heart of the matter is that EPA is
1544 moving toward the philosophy that there is no safe level of
1545 exposure to a chemical and this is contrary to the
1546 cornerstone of the science of toxicology. This change in
1547 philosophy results in unrealistically low regulatory levels.
1548 And as a result, naturally occurring levels of chemicals may
1549 be higher and often cases it is higher than EPA-safe level.

1550 As an example, using EPA's most recent draft assessment
1551 of formaldehyde, the formaldehyde in your breath that results
1552 from normal body functions would be over five times higher
1553 than the highest level that EPA would call safe.

1554 Formaldehyde is naturally formed in the air from the
1555 breakdown of chemicals released from vegetation, and
1556 according to available air data, the only places that would
1557 have safe air would be remote locations such as the arctic
1558 and South Pacific islands.

1559 In another example, using EPA's most recent draft
1560 assessment of arsenic, all fish and shellfish would contain
1561 levels of inorganic arsenic that are higher than the highest
1562 levels EPA would consider safe. And it is not just fish.

1563 Normal dietary food and drinking water consumption would also
1564 have arsenic levels substantially higher than EPA-safe level.
1565 And we just know that this isn't true. We aren't seeing the
1566 health effects that would be predicted or expected in the
1567 general population based on EPA's new values.

1568 While we do agree with EPA on being precautionary in areas
1569 where we don't have good science, we strongly believe that
1570 good science should not be ignored and should trump EPA's
1571 overuse of precaution. Hexavalent chromium is a good example
1572 of this. EPA's recent conclusion that ingesting hex chrome
1573 likely causes cancer in humans is based on a study where mice
1574 received extremely high levels of hex chrome, and EPA
1575 dismissed the human epidemiology and the wealth of other data
1576 that contradict this. And in those human studies, there was
1577 an occupational study where workers actually had yellow teeth
1578 and yellow tongues from ingesting so much arsenic.

1579 And TCEQ isn't the only organization concerned about the
1580 science behind EPA's recent assessments. The National
1581 Academy of Sciences, many prominent academic researchers,
1582 other states and other countries have noted the lack of good
1583 science in these assessments.

1584 Because of the lack of scientific defensibility and the
1585 implications of EPA's new chemical assessments, Texas has
1586 recently decided to develop our own chemical assessments. We

1587 have written two state-of-the-science guidance documents and
1588 had them externally scientifically peer reviewed by panels of
1589 imminent scientists, including scientists from EPA,
1590 California EPA, and Canada, and we are in the process of
1591 putting our latest document through a second round of public
1592 comment.

1593 We had no desire at all to use our limited resources to
1594 develop these chemical risk assessments that we have
1595 historically been able to rely on EPA for. However, the
1596 implications of EPA's new assessments have forced our hand.
1597 EPA's new assessments will unnecessarily scare the public and
1598 may actually harm public health by diverting public,
1599 industry, and government attention and resources away from
1600 public health issues that may pose more of a risk.

1601 As an example, EPA currently encourages pregnant women
1602 to limit their consumption of fish due to concerns of
1603 mercury. However, numerous recent studies show that the
1604 health benefit from pregnant women eating fish outweighs the
1605 potential risk for mercury. If EPA finalizes their draft
1606 arsenic value as it currently stands, then the public, the
1607 media, and advocacy groups would perceive fish as being even
1608 more unsafe resulting in even more pregnant women avoiding
1609 fish and its proven health benefits for them and their
1610 infants.

1611 There are also significant implications for remediation
1612 programs all across the country. Typical soil and water
1613 concentrations of chemicals, even some naturally occurring,
1614 would be considered unsafe. In other words, there is no safe
1615 place to live. How can you cling to below-background levels
1616 if background levels are unsafe? All replacement soils that
1617 we would use to fill in a backyard would also contain these
1618 unsafe background levels. So where are we going to put this
1619 so-called contaminated soil that we would have to dig up from
1620 somebody's yard?

1621 Your constituents will not stand for having soil and
1622 water that is deemed unsafe by EPA's new risk assessments
1623 even if it is naturally occurring and we can't do anything
1624 about it. So these are just some of the issues that we will
1625 have to face if EPA stays on their course, and I thank you
1626 for this opportunity to testify.

1627 [The prepared statement of Mr. Honeycutt follows:]

1628 ***** INSERT 4, 5 *****

|

1629 Mr. {Shimkus.} Thank you for your testimony.

1630 And now I would like to recognize Dr. Harvey Clewell.

1631 Sir, you have 5 minutes. And we are getting you fresh water.

1632 And you are recognized.

|
1633 ^STATEMENT OF HARVEY CLEWELL

1634 } Mr. {Clewell.} Thank you, Mr. Chairman. Good morning,
1635 Mr. Chairman, members of the subcommittee. My name is Harvey
1636 Clewell. I am the director for the Center for Human Health
1637 Assessment at the Hamner Institutes for Health Sciences in
1638 Research Triangle Park, North Carolina.

1639 In my position at the Hamner, as well as in my previous
1640 consulting positions, I have performed risk assessment
1641 research and consulting for a large number of government and
1642 industry clients, including the EPA. I am here today to
1643 present my professional opinions. I am not representing the
1644 Hamner or any other organization.

1645 I am very familiar with EPA risk assessment practices.
1646 Over the last 30 years, I have assisted EPA on risk
1647 assessments for a number of compounds including methylene
1648 chloride, cadmium, styrene, vinyl chloride,
1649 trichloroethylene, chloroform, and perchlorate. I have
1650 served on the EPA's FIFRA Scientific Advisory Panel and the
1651 recent EPA Science Advisory Board on IRIS assessments for
1652 dioxin. I have also served as a peer reviewer for a number
1653 of recent EPA guidelines, including those for cancer risk
1654 assessment and risk characterization.

1655 I consider EPA to be a leader in advancing risk
1656 assessment methods and have been favorably impressed by a
1657 number of recent IRIS assessments for which I was a peer
1658 reviewer, including those for one for dioxane and acrylamide.
1659 Nevertheless, I am concerned that the lack of objectivity and
1660 transparency in some recent IRIS assessments will impair the
1661 ability of decision-makers to make informed risk management
1662 decisions.

1663 I am particularly concerned that in some recent IRIS
1664 assessments, such as those for inorganic arsenic,
1665 formaldehyde and dioxin, only a single cancer risk assessment
1666 approach has been presented: a low-dose-linear default that
1667 assumes these chemicals are carcinogenic at any
1668 concentration. However, there is strong evidence for each of
1669 these chemicals that the true dose-response is nonlinear, and
1670 that the default greatly overestimates the actual risk at
1671 current human exposure levels.

1672 This IRIS practice of presenting only a single approach
1673 disregards the recommendation in the OMB memorandum entitled,
1674 ``Updated Principles for Risk Analysis,'' to provide a
1675 characterization of the dispersion of risk estimates
1676 associated with different models, assumptions, and decisions.
1677 The OMB principles provide valuable guidance for assuring
1678 that risk assessments adequately inform decision-makers faced

1679 with complex risk management options. Following the OMB
1680 recommendations should be a key objective of all IRIS
1681 assessments.

1682 The failure to objectively describe the evidence for
1683 alternative risk assessment approaches and to provide risk
1684 estimates other than the default has been a major deficiency
1685 in the IRIS risk assessment process. Even in the case of
1686 IRIS cancer assessments where alternative low-dose
1687 extrapolation options are discussed, there has been a clear
1688 bias towards presenting evidence that supports the selection
1689 of the default linear approach, even in cases where there is
1690 strong support for a nonlinear approach in the scientific
1691 community. Decision-makers would be better informed by a
1692 balanced and objective discussion of both alternatives and
1693 the presentation of analyses based on both alternative
1694 approaches in the risk characterization section of the
1695 assessment.

1696 As a justification for presenting only the default low-
1697 dose-linear risk assessment approach, the IRIS assessments
1698 have cited uncertainty in the evidence for alternative
1699 approaches. However, EPA guidance states that in the face of
1700 uncertainty, multiple approaches can be presented. The EPA's
1701 2005 Guidelines for Carcinogen Risk Assessment state that
1702 ``Nonlinear extrapolation having a significant biological

1703 support may be presented in addition to a linear approach
1704 when the available data and a weight of evidence evaluation
1705 support a nonlinear approach, but the data are not strong
1706 enough to ascertain the mode of action applying the Agency's
1707 mode of action framework. If more than one approach, e.g.
1708 both a nonlinear and linear approach are supported by the
1709 data, they should be used and presented to the decision-
1710 maker.''

1711 In a number of cases, NAS and the EPA Science Advisory
1712 Board peer reviews have requested that the IRIS assessment be
1713 modified to objectively present multiple risk assessment
1714 options but the Agency has not complied. I believe that the
1715 repeated refusal of the EPA to implement recommendations from
1716 the NAS and SAB peer reviews to objectively present
1717 alternative risk assessment options has greatly delayed the
1718 completion of the IRIS assessments for a number of important
1719 chemicals, in some cases for more than a decade.

1720 In addition to being inconsistent with agency guidance,
1721 presentation of only a conservative default approach when
1722 there is a viable alternative provides the decision-maker
1723 with an inaccurate characterization of risk that compromises
1724 his ability to make informed risk management decisions.

1725 In my opinion, IRIS assessments currently do not provide
1726 an objective and transparent characterization of the

1727 potential risks associated with chemical exposure. The
1728 inadequacy of the risk characterization in IRIS assessments,
1729 coupled with the sole use of conservative default approaches,
1730 hampers the ability of decision-makers to make informed risk
1731 management decisions and gives the public an inaccurate
1732 impression of their potential risks from chemical exposure.
1733 I believe that this deficiency could to a large extent be
1734 addressed by assuring that IRIS assessments adhere to the
1735 risk assessment principles elaborated in the OMB memorandum
1736 in the information quality principles.

1737 Thank you.

1738 [The prepared statement of Mr. Clewell follows:]

1739 ***** INSERT 6 *****

|
1740 Mr. {Shimkus.} Thank you. Now, I would like to
1741 recognize Mr. Cook for 5 minutes, sir.

|
1742 ^STATEMENT OF JERRY A. COOK

1743 } Mr. {Cook.} My name is Jerry Cook. I am the technical
1744 director of Chemical Products Corporation, a small 78-year-
1745 old Georgia corporation which employs about 200 people in
1746 Cartersville, Georgia, which is in the metropolitan Atlanta
1747 area, on the fringe I guess you would say. We are the last
1748 U.S. producer of barium chemicals and I have been dealing
1749 with barium toxicology and regulation for more than 28 years.
1750 I joined Chemical Products in late October 1982 as technical
1751 director.

1752 The IRIS database is supposed to determine sound science
1753 concerning the toxicology of chemicals to guide EPA's
1754 regulatory activities as we have heard today. If IRIS
1755 functioned properly, that could be used as a basis for sane
1756 regulation of various chemicals in the environment.
1757 Unfortunately, in the case of the IRIS barium file, I have
1758 found that the IRIS chemical managers and their superiors
1759 were not nearly as interested in sound science as they were
1760 in bureaucratic expediency. They simply did not want to hear
1761 sound science if it caused them to have to reevaluate the
1762 positions that they had previously taken.

1763 A brief history of barium regulation is as follows: in

1764 1975 in the statement of basis and purpose for the national
1765 interim primary drinking water regulations, under barium, EPA
1766 stated, ``No study appears to have been made of the amounts
1767 of barium that may be tolerated in drinking water or of
1768 effects from prolonged feeding of barium salts from which an
1769 acceptable water guideline may be set.'' They arbitrarily
1770 chose a value at that time based on the hypothesis that
1771 perhaps barium in drinking water could cause a small but
1772 significant increase in blood pressure and that that would be
1773 a danger to those already suffering from high blood pressure.
1774 That was a hypothetical effect that they derived from the
1775 fact that acute toxicity from barium salt ingestion does
1776 include heart effects including hypertension for the period
1777 of time until the barium is cleared from the body.

1778 The barium chemicals manufactured by Chemical Products
1779 Corporation are used in the ceramics industry to manufacture
1780 bricks and tiles, in the manufacture of luminous paints for
1781 highway signage and airport striping, and in heat treating of
1782 high-strength steel and the manufacture of catalysts. Many
1783 of our customers are small and medium-sized U.S. companies
1784 which are literally fighting for survival. Our customers
1785 tell us that the costs associated with retroregulation of
1786 barium are a substantial burden on them.

1787 In our efforts to change the retroregulation of barium,

1788 the IRIS determination of what was considered a safe level
1789 was cited as the reason why the retroregulations were not
1790 going to change. So that is how IRIS functions. IRIS is the
1791 basis upon which regulatory decisions are made. If the
1792 science in IRIS is bad, the regulatory decisions are going to
1793 be bad.

1794 The CEO of Summitville Tile, one of our customers, asked
1795 me to convey the following message to the members of this
1796 committee. ``The overregulation of American industry is
1797 making it increasingly more difficult for American
1798 manufacturers to compete in today's global economy.
1799 Summitville Tiles is a case in point. It is a 100-year-old
1800 manufacturer of quarry tile and brick products based in
1801 Eastern Ohio. In recent years, it has had to close 2 tile
1802 manufacturing facilities and 16 distribution centers, laying
1803 off over 450 employees. Summitville Tile is today one of the
1804 last American tile companies to remain in business. In fact,
1805 it is the only remaining charter member of the tile
1806 industry's National Trade Association, the Tile Council of
1807 North America. With foreign imports now comprising
1808 approximately 80 percent of the U.S. domestic tile market,
1809 the last thing that the tile industry needs is more
1810 regulations. What is needed more than anything else is
1811 regulatory relief.''

1812 I think that sums up the feeling of many of the small
1813 and medium-sized manufacturers in this country today. As a
1814 small or medium-sized company, they are really not equipped
1815 to deal with unnecessary regulatory burdens, and I think that
1816 that is exactly how I would characterize the regulation of
1817 barium because when a sound scientific study became available
1818 in 1994, when the NTP published a lifetime study of the
1819 effect of barium on rats and mice, IRIS greatly resisted
1820 acknowledging that study because it did not find the effect
1821 that was listed in IRIS. It did not find increased blood
1822 pressure. It instead found at much higher levels that barium
1823 would have an effect on the kidneys but the levels to find
1824 that effect were orders of magnitude higher than the level
1825 that was promulgated in IRIS.

1826 Let me tell you a little bit about barium if I may.
1827 Barium is an alkaline earth metal, one of the group which
1828 includes magnesium and calcium. It is not carcinogenic and
1829 barium is rapidly eliminated from the body. In cases of
1830 acute barium ingestion, the effects are usually gone within a
1831 week. Barium is widely dispersed in the natural environment
1832 in the mineral barite, barium sulfate, which is insoluble in
1833 water and acids. Because it is insoluble, barium sulfate is
1834 not toxic. This is the chemical administered as an x-ray
1835 contrast medium for gastrointestinal x-rays. The infamous

1836 barium meal, I have never had one, but I understand it is not
1837 particularly tasty. It doesn't matter which end you put it
1838 in, it works for gastrointestinal x-rays.

1839 If a large amount of soluble barium is ingested or
1840 inhaled, it is toxic because it temporarily interferes with
1841 the body's cellular potassium transport. EPA's IRIS database
1842 deals with chronic toxicity, which is a different situation.
1843 It is smaller amounts of a chemical consumed daily for many
1844 years over a lifetime. There is no known instance of any
1845 chronic toxic effect in a human due to barium and no animal
1846 studies were available as I read to you when EPA began
1847 regulating barium in the mid-1970s.

1848 Mr. {Shimkus.} Mr. Cook, I did tell folks they could go
1849 over 5. You are almost at 3 minutes over that so if you can
1850 kind of--

1851 Mr. {Cook.} Yes, sir. I appreciate it very much. I
1852 think you have gotten the gist of my situation.

1853 Mr. {Shimkus.} We have and we will follow up with
1854 questions.

1855 Mr. {Cook.} Thank you.

1856 [The prepared statement of Mr. Cook follows:]

1857 ***** INSERT 7 *****

|

1858 Mr. {Shimkus.} Thank you.

1859 The chair now recognizes Dr. Burke for 5 minutes.

|
1860 ^STATEMENT OF THOMAS A. BURKE

1861 } Mr. {Burke.} Thank you, Mr. Chairman. I appreciate
1862 this opportunity. I am Tom Burke and I am the associate dean
1863 and a professor at the Johns Hopkins School of Public Health,
1864 I also direct the Johns Hopkins Risk Sciences and Public
1865 Policy Institute, I served as a member of the Board on
1866 Environmental Sciences and Toxicology at the National
1867 Academy, I am a member of the EPA Science Advisory Board, and
1868 I chaired the National Academy report Science and Decisions,
1869 which really took a hard look at risk assessment practices at
1870 the EPA.

1871 Perhaps most relevant to today's hearing, though, is I
1872 have served as a state official. I was the director of the
1873 Toxics Program, the director of Science and Research at the
1874 New Jersey DEP, and the deputy health commissioner in charge
1875 of environmental issues in that State. So I worked closely
1876 with 4 governors on very challenging issues, responding to
1877 public health emergencies, which ranged from water
1878 contamination to contamination of our beaches to food
1879 contamination to the cleanup of hazardous waste sites.

1880 So as a frontline health official, I can tell you that
1881 risk assessment is really important. We need information

1882 when things bang in the night. And it is an essential tool
1883 for protecting the public's health. IRIS has been a part of
1884 that. So I would like to address 3 points today.

1885 One is risk assessment itself as an important tool.
1886 Second is the IRIS program, and the third I would like to say
1887 a little bit about, Science and Decisions and the National
1888 Academy recommendations to change the way we approach risk
1889 assessment.

1890 So first, as I mentioned, risk assessment is really
1891 important to public health officials and it is used by not
1892 just EPA but public health agencies around the world. I have
1893 helped most of our national agencies from DOD to USDA to use
1894 risk assessment. And as a state official, I have worked with
1895 other state officials in doing this. And EPA is recognized
1896 as providing most of us with the gold standards for
1897 evaluating hazards. Part of this is a tremendous use of the
1898 IRIS documents, but unfortunately, there are inherent
1899 uncertainties.

1900 And as you heard from the panel, there are lots of
1901 things about toxicology and epidemiology that are uncertain
1902 and they provide the basis for risk assessment. So for
1903 instance, does cancer in laboratory animals necessarily mean
1904 that exposure will cause cancer in humans? Or more
1905 appropriate perhaps in some of the debates about IRIS, if you

1906 have 2 conflicting studies, one says you see a health hazard
1907 and the other doesn't, which one does EPA go with and how do
1908 you make that decision? Well, there have been lots of
1909 arguments about this. There is lots of uncertainty that has
1910 led to a very polarized confrontation, as you might imagine.
1911 So I am no stranger to this phenomenon called dueling risk
1912 assessments. An agency will present their risk assessment
1913 and their approach to a problem and there is the opposite
1914 approach. And we have this situation where EPA is being
1915 called way to precautionary and industry's risk assessments
1916 aren't listened to because they are seen as not being
1917 protective of public health.

1918 So the challenge before us is this process itself, how
1919 to be more transparent, meet the needs of decision-makers,
1920 and break the log jam we now have. Now, the IRIS program, as
1921 you heard today, has a very unenviable task of synthesizing a
1922 lot of scientific information, and it appears to be the
1923 program everyone loves to hate. So they provide these very
1924 comprehensive overviews of health effects and they weigh the
1925 scientific evidence, and it is very important in determining
1926 if we have hazards. Not surprisingly, this is controversial.
1927 They are the starting point for many of the Agency's most
1928 difficult decisions. They provide insight into the magnitude
1929 of risk but they don't tell us how to manage risks.

1930 I am very familiar with the challenges of IRIS and I
1931 actually think the NAS report on formaldehyde provides a
1932 sound roadmap for them to improve that.

1933 Now, I would like to finish with a few words about risk
1934 assessment. We have blurred the line today I think between
1935 risk assessment and the IRIS hazard assessments. Risk
1936 assessment is about decisions and should start with, as
1937 Science and Decision lays out, the problem formulation making
1938 sure we ask the right questions, including the assessment
1939 that looks at the various options for control.

1940 And finally, with risk management decision
1941 justification, very important to this committee, is this
1942 decision justified, particularly in light of costs? So I
1943 think just to kind of sum up, the framework that Science and
1944 Decisions offers perhaps can help us improve the application
1945 of IRIS and risk assessment and risk management and consider
1946 the very important considerations of economics and jobs.

1947 So finally, can risk assessments work for jobs and the
1948 economy? Well, in my experience as a state official in New
1949 Jersey, a clean environment is definitely good for business,
1950 just ask the resort owners of the Jersey Shore or the
1951 businesses along the redeveloped Brownfields and the Hudson
1952 River shoreline. Getting better solutions for environmental
1953 problems goes well beyond IRIS and should focus on advancing

1954 risk assessment to better inform our public policies.

1955 Thank you for the opportunity to speak to you today.

1956 [The prepared statement of Mr. Burke follows:]

1957 ***** INSERT 8 *****

|
1958 Mr. {Shimkus.} Thank you, Dr. Burke.

1959 And now I would like to recognize myself for 5 minutes
1960 for opening questions in this panel. I will start with Mr.
1961 Cook because a lot of our focus here in this Congress has
1962 been on the effects of regulations on jobs and the economy.
1963 We do want to make sure that that is balanced, but we also,
1964 especially in the environment that we are in, we know that
1965 excessive regulations really are creating a burden.

1966 You have highlighted some of those burdens in your
1967 opening statement. If the chemicals you produce are not
1968 available, what substitutes would be made?

1969 Mr. {Cook.} In some cases, there would be substitutes
1970 available. In other cases, I am not sure there would be. In
1971 the case of the airport striping and signage, our barium
1972 carbonate is formulated by 2 manufacturers in the United
1973 States into very tiny barium glass beads. Barium gives that
1974 glass a very high refractive index, so when light shines on a
1975 paint containing these glass beads, it glows. I think that
1976 is a major safety consideration for airports and certainly it
1977 helps visibility of highway signs and probably has a safety
1978 impact there, too. I am not sure what material other than
1979 lead--lead glass also has a high refractive index.

1980 Mr. {Shimkus.} Barium would probably be better than

1981 lead.

1982 Mr. {Cook.} Given as I say there really is no chronic
1983 effect to barium until you get to very, very high levels that
1984 are just not found anywhere in nature.

1985 Mr. {Shimkus.} And let us just talk through this.

1986 Also, you opening statement mentioned if we are not certain
1987 that the IRIS analysis is based upon credible sound science,
1988 what effect does that have on you?

1989 Mr. {Cook.} Well, for the past almost 29 years now, I
1990 have been trying to effect a change in the regulatory limit.
1991 And as I said, that regulatory limit was established back in
1992 the '70s when there was no data. Unfortunately, when IRIS
1993 came along in 1987, by that point, EPA had funded two
1994 studies. One found a slight but--they claimed--significant
1995 blood pressure increase at low levels of barium in drinking
1996 water. The study in EPA's own health effects research lab,
1997 giving the rats 10 times as much barium for a longer period
1998 of time found no blood pressure increase. EPA chose to go
1999 with this study that found the blood pressure increase and
2000 said aha, here it is, once again, over-precautionary. It was
2001 not a particularly good study. They recognized that and yet
2002 they set their limits on that.

2003 Mr. {Shimkus.} And there is terminology, abundance of
2004 caution, at the different levels as the regulation moves

2005 forward, and I think you are highlighting that.

2006 Mr. {Cook.} Yes.

2007 Mr. {Shimkus.} Dr. Honeycutt, in your written
2008 testimony, you are pretty blunt. You say, ``because of the
2009 lack of scientific defensibility and the implications of
2010 EPA's new chemical assessments, we decided to develop our own
2011 chemical assessments.'' Can you describe the scientific
2012 defensibility that you refer to? Because I hear Mr. Cook
2013 talk about barium and I am not sure anyone in essence
2014 disagrees with that analysis, but can you talk about what you
2015 are referring to here?

2016 Mr. {Honeycutt.} Sure. There is no doubt that EPA
2017 comes up with safe levels. I mean there is no doubt about
2018 that. The question is can you have a higher level that is
2019 still just as safe? And that is where you have to get away
2020 from default procedures and actually look at how a chemical
2021 work in the body. How does it work in the rat versus how
2022 does it work in the human and then at what levels are they
2023 exposed to? Because chemicals will exhibit different levels
2024 of toxicity depending on the dose. A good example is
2025 Tylenol. Twenty tablets will kill you, two tablets will cure
2026 your headache, a half a tablet or a quarter of a tablet won't
2027 do anything to you that is an adverse effect. So you have to
2028 look at those differences in dose.

2029 Mr. {Shimkus.} In your opinion, is the IRIS program
2030 receptive to suggestions for program improvements to address
2031 this example you just gave?

2032 Mr. {Honeycutt.} Well, they actually have guidance on
2033 some of the things that we are talking about. The problem is
2034 their inconsistency in using their own guidance. They talk
2035 the talk but when it comes to doing the assessment, they just
2036 revert back to their old precautionary selves.

2037 Mr. {Shimkus.} Thank you. My time has expired. And
2038 depending upon how many people show up, we may go around a
2039 second time. I know there is more I want to address.

2040 So I would like to recognize Mr. Green for 5 minutes.

2041 Mr. {Green.} Thank you, Mr. Chairman.

2042 Both Houses of Congress seem to be interested in
2043 addressing the IRIS recommendations whether it is
2044 strengthening IRIS or suspending it. And our colleagues in
2045 the Senate sent a letter to one of our first panelists
2046 calling for suspension of IRIS assessments until the NAS
2047 recommendations can be incorporated. On the first panel, we
2048 heard from Dr. Anastas and the NAS on why such a suspension
2049 is not necessary and wouldn't protect public health. Now,
2050 with this panel, we are fortunate to have an expert on risk
2051 assessment who was quoted in that Senate letter.

2052 Dr. Burke, you are quoted as saying, ``A sleeping giant

2053 is the EPA sciences on the rocks and if you fail you become
2054 irrelevant.'' Would you explain that statement?

2055 Mr. {Burke.} Sure, and thanks for asking that question.
2056 So that statement was made at a meeting of the EPA Science
2057 Advisory Board where we presented with the ORD vision for how
2058 science will be conducted in the future. And knowing the
2059 incredible pressures and having been on those frontlines,
2060 applying science to society's problems, I issued that as a
2061 warning statement. Obviously, there is lots of criticism;
2062 then the credibility of science is really important.

2063 So why is EPA in a crisis? Well, because of the
2064 incessant attacks on their credibility not because they are
2065 not trying to put together the best science and not because
2066 they don't have a good Science Advisory Board that provides
2067 them, but I think it is important to put that into context.
2068 EPA is under siege. The very mission of protection of our
2069 environment is being questioned, sometimes with good cause
2070 because of the economic considerations. But I think there is
2071 a crisis. There is a crisis in credibility and that roadmap
2072 of improving IRIS will be a very important step toward
2073 addressing that crisis.

2074 Mr. {Green.} Okay. And you are familiar with the rider
2075 that I mentioned and do you think that rider would strengthen
2076 the IRIS program?

2077 Mr. {Burke.} Unfortunately, I think it would be a
2078 disservice to public health agencies throughout the country
2079 and even perhaps the world and it would bring things to a
2080 halt in a way that would not serve us well.

2081 Mr. {Green.} Okay. It seems there is a difference of
2082 opinion among our panel members on IRIS assessments and what
2083 they should be. Dr. Honeycutt suggested in his testimony the
2084 IRIS assessment provides EPA's judgment in how much a
2085 chemical can be in fish or apple juice for it to be
2086 considered safe, but these evaluations require assessing that
2087 exposure, something IRIS does not do. Dr. Burke, can you
2088 clarify the distinction between assessing the hazard and
2089 assessing the risk?

2090 Mr. {Burke.} Yeah, so understanding the hazard it is
2091 like knowing. So this is anthrax over here and this is bad
2092 stuff, can cause a real problem and it can cause problem at
2093 different levels. So it allows us to understand what the
2094 risks might be to people who are exposed. That is very
2095 different than the problem-oriented process of risk
2096 assessment that says we have a facility here that has a
2097 problem and potentially emitting things into the environment.
2098 How do we evaluate what is acceptable in terms of a response
2099 to manage that risk. So the risk assessment is site-
2100 specific; it is population-specific, very different than just

2101 identifying the hazard and evaluating the epidemiology and
2102 toxicology.

2103 Mr. {Green.} So there is a difference between the risk
2104 assessment and what risk is acceptable?

2105 Mr. {Burke.} Yes. And the hazard assessment will never
2106 tell you what risk is acceptable. That is a societal issue.
2107 It can consider social issues. There are lots of things that
2108 we don't regulate to very low levels because they are
2109 naturally occurring, and it is a policy question, not a
2110 science question except ability of risk. But understanding a
2111 hazard, that is all about good science.

2112 Mr. {Green.} Well, here we understand asbestos is a
2113 toxic substance but you can go out in some places and dig up
2114 asbestos since it is a rock. And we know we can't prohibit
2115 it because you can be exposed by just digging it up.
2116 Although asbestos for decades was used very substantially to
2117 retard fire risks, so an assessment of the danger and also
2118 what could be acceptable if you encapsulate it and do lots of
2119 things you can deal with that.

2120 Dr. Honeycutt, I want to thank you for appearing before
2121 the committee, and you have heard, I have worked with TCEQ
2122 over the years and TCEQ actually alerted our office because
2123 for years we have had a heightened dioxin level in upper
2124 Galveston Bay and the Houston Ship Channel and most of my

2125 industries are getting blamed for it. And there was some
2126 concern because we couldn't quantify it until TCEQ did. Can
2127 you tell us what efforts TCEQ has taken in regard to dioxin
2128 just as a substance? Like I joke I want dioxin, I want white
2129 shirts, but I also know that I don't want to drink it. So if
2130 you can tell us what TCEQ in Texas has done with it.

2131 Mr. {Honeycutt.} Yes, sir. Thank you. I am very
2132 familiar with the San Jacinto pit site. We have developed
2133 our own policy-based number that we have used over the years
2134 for dioxin, and as I mentioned in my testimony, we are
2135 developing our own procedures for coming up with these
2136 toxicity values that has been through a peer review and that
2137 is out for public comment right now. So once that is
2138 finalized, we are going to run dioxin through a process and
2139 see what our number looks like. So we are actively looking
2140 at that. I can't tell you right now where the number will
2141 come, whether ours is more or less or higher or lower than
2142 EPA's but we are going to be actively involved in that.

2143 Mr. {Green.} Okay. Is there going to be any conflict
2144 between when EPA is coming out in 2012 or will the TCEQ's be
2145 earlier than, you know, a year from now?

2146 Mr. {Honeycutt.} It won't be earlier than a year from
2147 now definitely.

2148 Mr. {Green.} Okay. It would be good to have two

2149 different assessments because, one, that is how you get what
2150 we can do with the risk and also I know I am over time but I
2151 appreciate your testimony that having spent 20 years in the
2152 Texas legislature and getting mad at EPA on a regular basis,
2153 we also recognize, as you said in your testimony, we sit down
2154 and can work things out but sometimes we have to lower the
2155 decibel level to get there.

2156 So thank you, Mr. Chairman.

2157 Mr. {Shimkus.} The gentleman yields back his time.

2158 The chair recognizes the gentleman from Louisiana, Mr.
2159 Cassidy, for 5 minutes.

2160 Dr. {Cassidy.} Thank you. I am an erstwhile academic
2161 so I will speak to Dr. Clewell and Dr. Burke because clearly
2162 as I gather IRIS is supposed to be here to use science to
2163 inform policy. The concern, though, is that policy is
2164 manipulating process in science to achieve an advocacy as
2165 opposed to achieving truth, truth being the highest calling
2166 of science. Fair statement? And that is, if you will, the
2167 question before us.

2168 Now, Dr. Clewell, when I read yours that there is clear
2169 bias towards presenting evidence that supports the selection
2170 of a default linear approach even when there is support for a
2171 nonlinear approach in the scientific community, if I was co-
2172 writing a paper with a medical student and she brought

2173 something to me that had only one explanation even though I
2174 knew that there was an alternative explanation which she does
2175 not address, I would give her a mulligan. I would say you
2176 are a medical student; you need to learn to do better. Bring
2177 it back discussing the alternative explanation and use this
2178 as a teaching moment. When EPA is using it to drive public
2179 policy, my blood pressure goes up. I must have just taken a
2180 boatload of barium because, you know, why in the world are we
2181 making decisions that affect an incredible number of jobs on
2182 something which doesn't have a plausible alternative
2183 explanation. So you have made your point.

2184 Let me ask Dr. Burke whether or not you disagree with
2185 the point Dr. Clewell made but by the way is a similar point
2186 to what NAS made that the neurobiological effects of the
2187 formaldehyde could be attributed to other things, which the
2188 thousand-page document did not discuss. So Dr. Burke?

2189 Mr. {Burke.} I don't think we fundamentally disagree
2190 that EPA should present as comprehensive a picture as
2191 possible with the alternatives. I think we probably disagree
2192 in the fundamental mission of EPA and there in my testimony--

2193 Dr. {Cassidy.} Can I stop you for a second?

2194 Mr. {Burke.} Yeah.

2195 Dr. {Cassidy.} Because I am actually talking about not
2196 EPA but IRIS.

2197 Mr. {Burke.} Okay.

2198 Dr. {Cassidy.} IRIS and a thousand-page document
2199 presumably presenting a comprehensive discussion--

2200 Mr. {Burke.} Right.

2201 Dr. {Cassidy.} --did not present a plausible
2202 alternative explanation that NAS came up with.

2203 Mr. {Burke.} Right.

2204 Dr. {Cassidy.} Now, this is not, you know, industry.

2205 This is NAS.

2206 Mr. {Burke.} Right.

2207 Dr. {Cassidy.} And so you open a thousand-page
2208 document, IRIS did not discuss it. It has to beg the
2209 question have they moved beyond advocating science for truth
2210 to selective presentation of science to pursue policy?

2211 Mr. {Burke.} Okay. Well, again, not being part of the
2212 IRIS program and not being part of that review, I know that
2213 the standard default that not just EPA but public health
2214 officials use, again, throughout the world particularly for
2215 carcinogens is the linear default, that we are not quite sure
2216 because genetic damage can happen at very low levels, just
2217 how low that straight line might go. However--

2218 Dr. {Cassidy.} Now, that I have to say surprises me
2219 because we know that a 20-pack a year history of cigarette
2220 smoking is strongly related to a risk of something less is a

2221 threshold effect. Indeed, Dr. Anastas spoke about how--I
2222 have it written down here someplace and of course I have lost
2223 it--that they look for a dose-related effect.

2224 Mr. {Burke.} Yes.

2225 Dr. {Cassidy.} So that would be a nonlinear effect. I
2226 am not sure why we are still mired in something conceived of
2227 3 decades ago as defining how we should approach a problem in
2228 this year.

2229 Mr. {Burke.} Well, I think it is the strength of
2230 evidence, and when we are looking at hormonal effects and we
2231 are looking at neurological effects on the unborn, the
2232 fundamental question is, a very important one, shouldn't we
2233 present the whole picture about what the alternatives may be.
2234 But that may not change the public health decision that where
2235 there is uncertainty we have to make decisions.

2236 Dr. {Cassidy.} But my concern is apparently they are
2237 not presenting the whole picture which in effect skews the--

2238 Mr. {Burke.} That is where I think we agree.

2239 Dr. {Cassidy.} Excuse the assumption. Dr. Clewell, I
2240 am kind of speaking for you. Could you speak for yourself?

2241 Mr. {Clewell.} Thank you, sir. I am particularly
2242 troubled because I worked closely with William Farland when
2243 they were developing the cancer guidelines trying to change
2244 from the old way of doing things with just a default. And

2245 the cancer guidelines was important because it was the first
2246 time that priority was given to a chemical-specific decision
2247 that did not rely on the default and a justification was
2248 required that there was insufficient data to support using a
2249 default. But in recent years there has been use of 1968
2250 guidelines. It is a default. They don't demonstrate a
2251 balanced presentation of the different alternatives that are
2252 being discussed in the scientific community. They paint a
2253 picture of evidence supporting the default.

2254 Dr. {Cassidy.} That is either suggesting incompetence
2255 or it is suggesting the pursuit of a political agenda.

2256 Mr. {Clewell.} Absolutely not incompetence. They are
2257 very competent people. I believe that they are public health
2258 professionals who are very concerned about public health and
2259 want to make sure they are conservative. And in trying to
2260 make sure that the protection is provided, they may not
2261 provide complete descriptions of alternative approaches that
2262 would generate a lower-risk estimate.

2263 Dr. {Cassidy.} That is a patronizing approach to the
2264 use of truth in science. And I as a person who is sitting on
2265 here trying to make an informed decision am offended that
2266 they assume I don't have the intellectual firepower to figure
2267 it out. And that is a disservice to the American people.

2268 Mr. {Clewell.} Actually, the Office of Water has the

2269 same problem. They are pretty much hamstrung by the arsenic
2270 risk assessment and decisions they would like to make like
2271 saying you don't have to clean up the entire western country
2272 of arsenic in soil and river water are difficult to make when
2273 there is only a linear risk estimate.

2274 Dr. {Cassidy.} I agree with Dr. Burke that there is
2275 indeed a threat to IRIS's reputation and I think we are
2276 seeing it in terms of an uncovering of how they present
2277 facts. I yield back.

2278 Mr. {Shimkus.} The gentleman yields back his time.

2279 For the sake of getting my colleagues angry at me, I
2280 would like to go to a second round. I think the panel is
2281 well informed. We are learning a lot. The risk will be
2282 members may come back which might hold you a little bit
2283 longer, but I would like to go a second round if that is okay
2284 with our guests and my colleagues here. If no objection,
2285 then so ordered. We will go to a second round, 5 minutes
2286 each. And I may not take my whole 5 minutes, but with that,
2287 I will recognize myself.

2288 And this is just a great debate. My concern is an
2289 overabundance of caution at IRIS and an overabundance of
2290 caution at EPA with the policymakers could create job loss,
2291 economic dislocation, and movement of production overseas.
2292 So we have got to get the science right and I don't question

2293 the public health officials' intent to protect human health.
2294 I do agree that this debate on dosage and what is really
2295 harmful is very, very important.

2296 So with that, Dr. Burke, I want to address just one
2297 question on the delay because the question is what would you
2298 deem more harmful to human health and the economy? A 1- or
2299 2-year delay in an assessment that would ensure the
2300 scientific robustness of the result or an assessment based on
2301 poor processes that is pushed through with questionable
2302 science?

2303 Mr. {Burke.} I think we owe it to the American public,
2304 I think we owe it to the scientific community to use the data
2305 appropriately and to synthesize the scientific information to
2306 inform decisions. However, having been in emergency
2307 situations where the data wasn't perfect, for instance, the
2308 trailers in Louisiana where the data on formaldehyde weren't
2309 perfect, I worked with the CDC to try and make sure we didn't
2310 have acute exposures. So sometimes in public health we have
2311 imperfect information. However, I agree with you, Mr.
2312 Chairman, that it would be better to do it right than to
2313 destroy the credibility of the process.

2314 Mr. {Shimkus.} And that is this whole debate from the
2315 Senate, from what we did on the rider to say let the National
2316 Academy of Sciences' report be, you know, followed before we

2317 continue to move forward just so we get it right. But the
2318 great thing about a lot of things we do on this committee and
2319 on our health subcommittee is that people in this arena are
2320 public servants and want to do things right. But again we
2321 wanted to raise that issue.

2322 To Dr. Honeycutt, I raised this in maybe my opening
2323 statement or the first round. We have talked about it before
2324 and we just mentioned it with the water and arsenic in the
2325 Southwest. I remember it well because one of my colleagues,
2326 Heather Wilson, always talked about that, arsenic levels in
2327 drinking water although it was naturally occurring. So with
2328 that, this question, in your opinion are there broader
2329 economic consequences associated with publishing an IRIS
2330 value that is lower than background levels, and if so, what
2331 impact do you feel it has on the jobs in the economy?

2332 Mr. {Honeycutt.} Oh, absolutely there is an impact.
2333 Two real quick examples, one is mercury. EPA is actually,
2334 they are outliers from the rest of the world and what is a
2335 safe level of mercury in fish. All other regulatory agencies
2336 have higher safe levels. And they came home to Texas just a
2337 few weeks ago.

2338 Mr. {Shimkus.} Let me interrupt. Is that true in the
2339 European standards?

2340 Mr. {Honeycutt.} Yes, the World Health Organization has

2341 a higher safe level for mercury in fish than EPA does.

2342 Mr. {Shimkus.} That is funny. I never hear my
2343 colleagues mention that when we debate that issue.

2344 Mr. {Honeycutt.} But Lumina Energy laid off 500 people
2345 just a couple of weeks ago. So it does have direct or
2346 indirect--it depends on how you look at it--economic
2347 consequences.

2348 And another example is the arsenic that you are talking
2349 about. In Texas, there are a lot of really small locally
2350 owned utilities that won't be able to meet this, so they are
2351 going to close down. And so people then will have to drill
2352 their own water wells and that is a real public health
2353 concern because that water won't be tested or monitored and
2354 they are going to be at their own risk that the public water
2355 systems won't be able to provide that level of safety.

2356 Mr. {Shimkus.} And let me just finish by this. Mr.
2357 Cook talked about barium quite a bit in his analysis and his
2358 response. His statements on barium and the health risk--and
2359 I kind of assumed everyone sort of agreed with that analysis--
2360 -can you go on record saying you agree with Mr. Cook on his
2361 analysis on barium?

2362 Mr. {Honeycutt.} Yes, sir. Barium in the grand scheme
2363 of things is not a very toxic chemical at all.

2364 Mr. {Shimkus.} Dr. Clewell?

2365 Mr. {Clewell.} Yes, I agree.

2366 Mr. {Shimkus.} Dr. Burke?

2367 Mr. {Burke.} I really don't know the issue. I will
2368 have to--

2369 Mr. {Shimkus.} That is fine. That is fine. And that
2370 is why I wanted to clarify because I did make an assumption.
2371 I didn't want to do that.

2372 So I am going to yield back 18 seconds and ask my
2373 colleague, Mr. Green, to be recognized for 5 minutes.

2374 Mr. {Green.} Thank you, Mr. Chairman.

2375 Dr. Burke, in listening to my colleague from Louisiana,
2376 Dr. Cassidy, and I think your comments sound like it blurs
2377 the line between the mission of IRIS, which is to assess the
2378 risk and not the issue of regulations, which is the
2379 management of that risk, which is EPA's job. I guess there
2380 may be some concern that by the assessment from IRIS, it may
2381 raise the level of concern but, you know, like we have heard
2382 from Dr. Honeycutt, you know, IRIS is supposed to give the
2383 assessment but the risk is an EPA decision and not
2384 necessarily what may come out of the study.

2385 For example, the water, you know, obviously water we
2386 need for our lives, but if you take it from a fire hose, you
2387 are going to drown. And so there is a reasonable amount that
2388 you can have that is necessary but it is, you know, too much

2389 of anything is bad.

2390 And Dr. Burke, naturally occurring levels of chemicals,
2391 they are not always safe. A good example of arsenic in
2392 water, I can tell you in West Texas and all over the West
2393 there are waterholes or water that people should not drink
2394 and know they shouldn't drink because of whatever the
2395 chemical is in there that are naturally occurring. So just
2396 because they are naturally occurring doesn't mean it is safe.
2397 You just have to have a certain level of it I guess to keep
2398 it. And is that something we are continually confused, the
2399 difference between assessment and risk?

2400 Mr. {Burke.} Well, it is a very important point. We
2401 can't possible clean up the Earth's crust, nor can we
2402 regulate volcanoes for spewing mercury. And we have these
2403 naturally occurring materials and we have to balance that in
2404 the decision-making. On the other hand, what we know about
2405 arsenic comes from actually naturally occurring contaminated
2406 wells in other parts of the world where people drank very
2407 high amounts and had acute effects as well as cancer effects.
2408 And so it comes down to being reasonable about how we
2409 approach regulation with the right information on the public
2410 health effects to help us make those decisions.

2411 Mr. {Green.} Okay. You know, I have announced where I
2412 come from. I have the biggest petrochemical complex in the

2413 world in our district--in the country, second largest in the
2414 world, and so I guess my focus is on the relationship. Dr.
2415 Burke, as a former state regulator and you have seen the risk
2416 assessment and effective risk management, what effect can it
2417 have on the jobs? Every product we make in the Houston Ship
2418 Channel, it wouldn't be made if somebody didn't need it. I
2419 mean industries don't do that. They don't make any money on
2420 it. So someone needs it but it depends on how you make it
2421 and how that product is used, whether it be in gasoline or
2422 some other additive or something else.

2423 But is there a direct correlation between effective risk
2424 management and the impact on jobs and the economy, which is I
2425 think what the whole subcommittee was getting at?

2426 Mr. {Burke.} I think that is a very important point in
2427 major regulatory decisions. I am not an economist. I can
2428 only speak from experience, and clearly there are regulations
2429 that have added cost to industry and therefore may impact
2430 jobs and may impact the general public as well. But as we
2431 recommended in Science and Decisions, that should be part of
2432 the deal in conducting the assessment to make sure you are
2433 making the right risk management choice.

2434 That doesn't change what happens in the epidemiologic
2435 studies or in the mice, but we can take that data and if it
2436 is properly presented make good decisions. So in my

2437 experience again, New Jersey, very industrialized, lots of
2438 heavy industry, lots of refineries, pollution was much worse
2439 for jobs and unsafe workplaces were much worse for jobs than
2440 environmental regulations. However, I completely understand
2441 that analyzing the impacts on the economy on jobs should be
2442 part of the decision process.

2443 Mr. {Green.} Thank you, Mr. Chairman. And following
2444 your lead, I will yield back my 46 seconds.

2445 Mr. {Shimkus.} I thank my friend.

2446 The chair now recognizes the gentleman from Louisiana,
2447 Mr. Cassidy, for 5 minutes.

2448 Dr. {Cassidy.} Again, I am learning a heck of a lot in
2449 this meeting, so thank you all for all being here. I am
2450 struck how sometimes processes used to manipulate the
2451 response to the findings. Now, Dr. Honeycutt, I am impressed
2452 that you all--I haven't read about a regression coefficient
2453 since I have been here, you know, been practicing whatever,
2454 and you all did an analysis--now, that is a 1,043-page
2455 document which is stultifying, redundant, and sometimes
2456 irrelevant, and yet you had to do all 1,043 pages. Now, it
2457 makes me think that it would be incredibly time-intensive,
2458 resource-intensive to really do an adequate review. If you
2459 have a statistician doing a regression coefficient on
2460 nasopharyngeal cancer mortality to criticize or critique the

2461 method by which they determined incidents, you got some money
2462 tied up in staff working on this project. Fair statement?

2463 Mr. {Honeycutt.} Yes, sir, it is.

2464 Dr. {Cassidy.} Now, if it is 1,000 pages do they give
2465 you 120 days or--do you see what I am saying?

2466 Mr. {Honeycutt.} Yes, sir. No, you get the same amount
2467 of time. And the deal with IRIS is you don't get to give
2468 input on the front end; you give input on the back ends after
2469 EPA has already--the train has left the station and they are
2470 recalcitrant to change their mind. So that is what you are
2471 left with.

2472 Dr. {Cassidy.} I see everybody nodding their head yeah.
2473 Now, that is disturbing because again if we have a premise
2474 which I think you all agree with is that sometimes they are
2475 not given the complete picture but at the same time it takes
2476 an incredibly intensive process in order to uncover how that
2477 is not complete, then you are going to have policy decisions
2478 made upon something which may, some cynics would say,
2479 deliberately made onerous upon which to review. Again, it
2480 goes back to is science deriving policy or is science being
2481 presented in such a way as to serve as advocacy for a policy
2482 end?

2483 Now, we heard in the first panel and NAS and others
2484 criticize the fact that OMB was allowed to at times review

2485 the EPA documents in order to say, okay, wait a second, time
2486 out, let us look at this. But Dr. Burke, I had a sense from
2487 you that in this whole analysis needs to be some sort of
2488 cost-benefit return on investment, what is the true sort of
2489 economic cost? Here we have people losing their jobs for
2490 something which is nominally and maybe even speciously toxic.
2491 Now I am thinking maybe OMB needs to be involved. I mean
2492 maybe there needs to be a delay if once the train has left
2493 the station you have so little time to review something which
2494 is so complex to review.

2495 Dr. Clewell, what would be your comments on that?

2496 Mr. {Clewell.} I am not what sure what would be the
2497 level of oversight, but I do believe that OMB plays an
2498 important role in verifying that the agencies are doing the
2499 best job to make the process reviewable, and so I would be in
2500 favor of there being a better dialogue between OMB and EPA so
2501 that that could be accomplished.

2502 Dr. {Cassidy.} And in fairness, I think the critique is
2503 that they should be more transparent in their questions, but
2504 I think there was also a criticism as regards sending EPA
2505 back to repeat an analysis. What I have learned today is
2506 that maybe EPA does need to be sent back to be more inclusive
2507 in their analysis. I am feeling more sympathy for OMB right
2508 now. So let us see if there is anything else in this.

2509 Now, who is a chemist? Anybody up there a chemist? The
2510 idea that Dr. Anastas said that with green chemistry they
2511 know the actual effect of every chemical compound is going to
2512 have upon skin, respiratory system, digestive system, et
2513 cetera seems to me like the epitome of intellectual kind of
2514 hubris.

2515 Mr. {Clewell.} It might have been somewhat hyperbolic.
2516 I think he is trying to indicate that there is an ability--
2517 and drug companies use it all the time--to try to estimate
2518 activity from structural properties and that is trying to be
2519 harnessed. They are trying to harness that in order to
2520 develop safer compounds.

2521 Dr. {Cassidy.} There is also the presumption, though,
2522 that you can make everything inert, and I am not sure you can
2523 make life inert.

2524 Mr. {Clewell.} I am fairly confident you cannot.

2525 Dr. {Cassidy.} Yeah, so I agree with that.

2526 Let me finish up. I will also yield back by saying to
2527 Mr. Cook, Mr. Cook, you are the only guy in this whole room
2528 that creates jobs, so on behalf of the American people, thank
2529 you for creating jobs, and I am very sorry for the
2530 impediments put in front of you by the Federal Government.
2531 We sincerely wish we could be creating a lot more jobs.

2532 Thank you. I yield back.

2533 Mr. {Shimkus.} The gentleman yields back. At this
2534 time, the chair now recognizes Mr. Harper from Mississippi
2535 for 5 minutes.

2536 Mr. {Harper.} Thank you, Mr. Chairman. And thank you,
2537 witnesses, for being here today and giving your insight into
2538 what is continuing to be a very important issue for us.
2539 And I will start if I may with you, Dr. Honeycutt, if I could
2540 just with some follow up questions on what you had earlier.

2541 And I have to ask what types of evidence are necessary
2542 to establish a causal relationship between exposure to a
2543 substance and some health effect or health risk. What are
2544 you looking for?

2545 Mr. {Honeycutt.} Yes, that is a very good question and
2546 it is well known. It is called the Hill criteria for
2547 causation. It is well documented. What you need to do is
2548 show that a chemical can cause the effect that you are
2549 looking at and it can cause it at the concentrations you are
2550 looking at and that it is reproducible. It happens over and
2551 over again, not just one time in one study, and that the
2552 effect happens after the exposure. Sometimes we regulate
2553 chemicals on if the effect happens before the exposure.

2554 Mr. {Harper.} Um-hum.

2555 Mr. {Honeycutt.} And that it is not just a background
2556 occurrence, the health effect that you are looking at, that

2557 if there is an increased incidence of cancer in this
2558 community that it is indeed increased, it is well above
2559 background, not just a tiny bit above background.

2560 Mr. {Harper.} Are you always able to figure those
2561 problems out? It is a search I am sure many times.

2562 Mr. {Honeycutt.} Sometimes it happens very easily and
2563 sometimes it is harder. The health effects of ozone are
2564 based on a 1 to 4 percent increase in premature mortality,
2565 whatever that is, and how do you quantitate that? It is
2566 very, very difficult. And in studies the EPA use, you can't
2567 quantitate that.

2568 Mr. {Harper.} And is it true that substances at a high
2569 level which may create that risk, they may be safe, perhaps
2570 even necessary at a low level. Would that be certainly true
2571 to say?

2572 Mr. {Honeycutt.} Absolutely. Every vitamin you take,
2573 most of the minerals in your food that you eat, some of them
2574 are essential nutrients that if you get too much of them,
2575 they will kill you.

2576 Mr. {Harper.} If I could, Dr. Cook, I wanted to ask
2577 you--

2578 Mr. {Cook.} Mr. Cook.

2579 Mr. {Harper.} Mr. Cook, I am sorry. That just shows
2580 you the respect that we have for your being here today.

2581 Earlier today we had on the first panel--I believe you
2582 were in the room when they were here--Mr. Trimble from GAO
2583 testified on panel one that the EPA should take the IRIS
2584 program back in-house to avoid meddling from OMB or other
2585 departments or agencies. Based upon your experience, do you
2586 think that is a wise move?

2587 Mr. {Cook.} If it had not been for OMB's implementation
2588 of the Information Quality Act in 2002, I do not believe we
2589 ever would have seen IRIS recognize the true chronic effect
2590 from barium. Four years after the 1994 NTP study, the
2591 definitive study was published on barium chronic toxicity,
2592 the revised IRIS assessment in 1998 still argued and ignored
2593 the sound scientific evidence that there was no blood
2594 pressure effect from small low levels of barium, if it had
2595 not been for OMB's intervention, I don't think we ever would
2596 have gotten any response from EPA to make the change that was
2597 finally put into effect in IRIS in 2005.

2598 Mr. {Harper.} Thank you. Also, Mr. Cook, another
2599 question I have is, you know, some concerns about IRIS relate
2600 to cleanup levels that must be attained under our federal
2601 environmental laws. Do you have any experience where IRIS's
2602 uncertainty or inappropriate values caused a hazardous waste
2603 cleanup to either stall or be delayed or the costs rise
2604 substantially?

2605 Mr. {Cook.} We are still in the throes of determining
2606 financial responsibility for a superfund cleanup that is
2607 still ongoing in North Carolina. Ward Transformer Company
2608 operated just near the Raleigh, North Carolina, Airport
2609 rebuilding transformers from 1963 until they finally went out
2610 of business I think in 2004. They were designated as a
2611 superfund site, the plant site there I think in about 1979.
2612 Some of the potentially responsible parties negotiated a
2613 settlement with EPA to clean up the actual plant site. The
2614 contamination is all PCBs from transformer oil. And they
2615 were given a choice at the time that they came to a
2616 settlement with EPA of either cleaning up to a 25-parts-per-
2617 million standard or a 1-part-per-million standard. The
2618 consultant that was working with them reported in the
2619 document that I obtained from Region 4 EPA that the choice to
2620 clean up to a very stringent 1-PPM standard was made
2621 primarily because of a fear that EPA would come back later
2622 and require a further cleanup because the safe level had not
2623 been clearly defined in IRIS and they were not sure what
2624 might come down the pike.

2625 Mr. {Harper.} So an abundance of caution made them do
2626 that at a much greater cost than probably what was necessary.

2627 Mr. {Cook.} Yes. I think they even ended up spending
2628 about 2-1/2 times what they thought they were going to spend

2629 to clean up to a 1-PPM standard.

2630 Mr. {Harper.} I thank each of you and I yield back.

2631 Mr. {Shimkus.} I thank my colleague for joining and for
2632 you, thank you for putting up with 2 rounds of questions from
2633 us. We really appreciate it. And you can tell from the
2634 questions by my colleagues that they were sincere in trying
2635 to work through this process.

2636 I want to put on the record that the record will be open
2637 for 10 days. You all may see some additional written
2638 question as the first panel might from us. If you could
2639 answer those questions in writing and send them back within
2640 that period of time or as soon as possible, we would greatly
2641 appreciate that. We do appreciate your time and I adjourn
2642 the hearing.

2643 [Whereupon, at 1:02 p.m., the subcommittee was
2644 adjourned.]