# **Get Plastic Out of Your Diet**

by Paul Goettlich

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#### You Are What You Eat

When you eat or drink things that are stored in plastic, taste it, smell it, wear it, sit on it, and so on, plastic is incorporated into you. In fact, the plastic gets into the food and food gets into the plastic and you. So, quite literally, you are what you eat  $\{1\}$  ... drink .. and breathe - plastic! These plastics are called "Food Contact Substances" by the US Food and Drug Administration (FDA), but until April 2002, they were called "Indirect Food Additives".  $\{2\}$  The new name is cleansed of the implication that plastic gets into your food. In spite of this semantic deception, migration is a key assumption of the FDA.

According to Dr George Pauli, Associate Director of Science Policy, FDA Office of Food Additive Safety, the regulations mandated in 1958 assume that all plastics migrate toxins into the food they contact. Migration is the movement of free toxins from plastic into the substances they contact - in this case it's your food. The manufacturer must "prove" that the migrations fall within an acceptable range. {3} I agree with the assumption of migration from all plastics, but I find a critical disparity between the level of science employed by the regulations and the current scientific knowledge regarding the levels at which they migrate and the effects they can have. In particular, I am more concerned with extremely low concentrations. There is also a conflict of interest in allowing the manufacturer to submit its own testing to the FDA as proof of anything. We invite the fox into the henhouse and are surprised when there's nothing left but eggshells and feathers.

The amount of migration and corresponding toxicological effects are highly disputed topics, even within the FDA, which has commonly acquiesced to industry in its regulation of technologies that are used in the production of our foods - plastics, pesticides, growth hormones, irradiation, and microwave. This is clear from the mass of expert and citizen testimony against such technologies that regulatory agencies bend over backwards and jump through flaming hoops to please their corporate clients, as they are called.

There is a worst plastic for any purpose - polyvinylchloride (vinyl or PVC). However, there is no best plastic to contain food or drink. It is my hope that this article will clarify this viewpoint. By the time you've finished reading, you should be closer to forming your own evaluation of plastics.

## Its Uses

Plastic is used in contact with nearly all packaged foods. Most cardboard milk containers are now coated with plastic {4} rather than wax. It is sprayed on both commercial and organic produce to preserve its freshness. Plastic is even used to irrigate, mulch, wrap, and transport

organic food. Organic bananas now come from wholesalers with a sticky plastic wrapping the cut stem to protect the bananas from a black mold. {5} The mold is controlled on non-organic bananas by dipping the cut ends in a fungicide. Chiquita would only reveal that it's a "food grade plastic", which means that it meets minimum regulatory standards. But since it has a sticky feel to it, I suspect it either carries a fungicide or its physical characteristics act as a fungicide. Either way, if it is or acts as a fungicide, the EPA regulates it as a pesticide, which fungicides are considered a subset of. {6} In a way, this is similar to the regulation of corn that is genetically engineered to carry the toxic bacterium bacillus thuringiensis (Bt) in every cell. Rather than the FDA regulating it as a food, the EPA regulates it as a pesticide. Incredible as it may seem, they see our food as a pesticide.

According to the FDA scientist I spoke with, it's a proprietary formula that he doesn't know about and would offer nothing beyond that. Disclosure of proprietary information is a criminal offense. {7} All plastic manufacturers hide behind trade secrets. This is true with nearly all consumer products. It is quite impossible to know the chemical makeup of any plastic without paying a substantial amount of money for an independent lab analysis.

#### How is it made?

In a nutshell, plastic is made by combining monomers into polymers under great heat and pressure in a process called polymerization. Each manufacturer has its own proprietary formula for each plastic. And each uses a variety of additives such as plasticizers for flexibility, UV filters for protection from sunlight, antistatic agents, flame-retardants, colorants, antioxidants, and more. Heavy metals such as cadmium, mercury, and lead are common additives. There are also chemicals used to facilitate production such as mold releases, and countless other toxic chemicals regularly added to plastic consumer goods without our knowledge or approval. Many of the products and byproducts of the intermediary steps of plastics production are used in other plastics or industrial processes and products such as pesticides or fertilizer. For holistic thinkers, the mention of plastics and pesticides in the same sentence should begin an informative thought process, while keeping in mind that they all have complete regulatory approval.

#### The True Cost of Plastic

Plastic is ubiquitous in our lives because it is convenient and relatively inexpensive. It is advertised as safe and that it saves lives. {8} Its safety is based on outdated science and regulations. And while it saves lives in the short run, the record against plastic is looking quite different.

Its convenience comes from being lightweight and its ability to absorb impact shock without breaking, which on its own merit, is hard to argue with. It comes in an endless range of colors and finishes, is pliable, and is easily formed and molded. Most would say it's a perfect material, right? Here's where the bad news begins.

Its inexpensiveness is the result of a large portion of the costs associated with its life - production, use and disposal - being put onto society as a whole. This unsolicited financial burden on society manifests itself as increased taxes to finance municipal curbside recycling programs, landfill space, and incineration. It also increases health care and insurance costs as a

result of its incineration polluting the air, water, and food. I'll give much more detail on the negative health effects later, but for now, suffice to say that a full and truthful lifecycle analysis would reveal that the long-term negative health and socioeconomic effects at the local and global scales far outweigh the benefits realized by the use of plastics.

## What's so bad about plastic?

For decades, the plastics industry has deceived us with assurances that the polymerization process binds the constituent chemicals together so perfectly that the resulting plastic is completely nontoxic and passes through us without a hitch. In spite of this industry disinformation, {9} the polymerization process is never 100% perfect. Logically then, there are always toxicants available for migration into the many things they contact - your food, air, water, skin, and so on. Both the FDA and the industry know this. However, because of many millions of dollars worth of advertising and public relations work, consumers are educated to think that plastics are safe.

The additives utilized are not bound to the already imperfect plastic, leaving them quite free to migrate. One quick example: without a plasticizer additive, PVC would be rigid. The plasticizer resides between the molecules of the PVC, acting as a lubricant that allows those molecules to slide by each other, and thus flex. Many containers used for food or water are made of it. Even Barbie dolls are made of it. The plasticizer migrates out from day one. And as it ages, the migration can visibly weep out of it. {10}

Plastics, their additives and other processing chemicals can be toxic at extremely low concentrations. In fact, some are significantly more toxic at extremely low concentrations than at much higher concentrations, which is contrary to the FDA scientist's paradigm that, "The dose makes the poison", meaning that the higher the concentration, the more toxic something is. It is an interpretation of the writings of Paracelsus, an alchemist who wrote in the 16th century that, "Alle Ding sind Gift und nichts ohne Gift; alein die Dosis macht das ein Ding kein Gift ist" [All things are poison and nothing without poison; alone it is the dose that makes a thing no poison]. {11} It's now 500 years later and that assumption of Paracelsus is still the basis for the many regulations. Except on chemical-by-chemical investigations by various independent, institutional, and academic labs, plastics are not explored for harmful effects or regulated in any meaningful way.

## Extremely Low Doses and Synergy

Since it is known that all plastics migrate into food, it behooves us to look for the evidence at meaningful levels of detection, at and below single-digit parts-per-trillion (ppt) or ng/kg. Extremely low doses are especially relevant because they can upset the natural balance of the endocrine system. To paraphrase the report of an EPA workshop in 1996, endocrine disruptors (EDs) are external agents that interfere with the production, release, transport, metabolism, binding, action or elimination of natural hormones in the body responsible for maintaining internal balances and the regulation of developmental processes. {12}

Current knowledge of EDs turns the work of Paracelsus - that guy born in the 15th century - upside down. Some chemicals can be more toxic at extremely low doses than extremely high

doses. The timing of the exposure can be much more relevant than its dose. Most vulnerable times are in periods of rapid growth, such as those in embryo and children right up to puberty. They can be exposed in the womb and before conception, if sperm and/or ovum are contaminated. The maladies of the children of Gulf War veterans are a prime example of this type of exposure. {13}

Synergy is an important issue that is mostly disregarded by the FDA. Many will even debunk the idea that low dose synergy is real. In combination with other commonly used products, the toxicity of the migratory chemicals from plastics can be potentiated by synergy. A synergy can occur between two or more chemicals that elevate the combination's toxicity to hundreds of times greater than that of the individual chemicals. Besides plastics, other household chemicals can be part of a synergy with plastics.

Nuclear radiation can also severely damage the endocrine system. According to Dr Ernest Sternglass, Professor Emeritus of Radiological Physics at the University of Pittsburgh Medical School, the synergy between nuclear radiation and chemical toxicants is well documented. {14} Gulf War vets (I and II) were and still are being exposed to depleted uranium (DU) from the tons of armour-busting shells they fired being distributed across the Gulf Region as an aerosol smaller than the size of a virus. {15} The hazardous materials (MOPP) suit that soldiers are given do not protect them from the infinitesimally small particles of DU because the high efficiency particulate air (HEPA) filters do not work below 1/10 of a micron. Each one of us is exposed to extremely low levels of radiation from the nuclear power plants scattered about the US. {16}

On the home front, even the products in our day-in and day-out humdrum lives are coated with, contain, or are made of synthetic chemicals that can interact synergistically with each other. The list is endless but includes beauty products such as nail polish, eyeliner, deodorant and aftershave; household cleaning products such as tile and carpet cleaners, air fresheners that are solid, plug-in, or spray. Even gas and diesel engine exhaust are included. Quite frankly, the FDA doesn't even consider all sources of a chemical in its review of industry product applications.

Consider that there between 87,000 to 100,000 chemicals in commercial production. At the time I wrote this, there were 22,241,247 organic and inorganic substances registered with Chemical Abstracts Service (CAS) registry. {17} Only eight months before that, there were 1,112,474 fewer chemicals. {18} They are regulated and tested in what I would call a "don't look - don't see" style of science that boggles the minds of those who look just a little below the surface of the happy little corporate-science myths. The focus is on the wonders of plastic with a purposeful avoidance of the painfully evident negative human and environmental health effects. Using the more conservative 87,000 chemicals, there are approximately 1.063725377 x 10 to the 86,991st power different combinations possible that could have a synergistic effect on toxicity. {19} For the purposes of this article, that number is roughly 1 with 87,000 zeros after it. Even if researchers had the time and money to test them all, they still wouldn't know what to look for, because there is no precedent. In addition, one must account for the uniqueness of each living organism and its unique environment, which further expand the possible synergies and possibilities.

#### Water Stored in Plastic

Water bottles are be made from various types of plastic - polycarbonate (PC), polyethylene terephthalate (PET), Polypropylene (PP), high-density polyethylene (HDPE), low-density polyethylene (LDPE), polyvinyl chloride (PVC or vinyl), and others. To reiterate, they all migrate to some degree. I will focus on just one chemical that migrates out of one plastic that is used to make products with high use and sales profiles.

Bisphenol-A (BPA) is a monomer used in the synthesis of PC plastics, epoxy resins, and composites, as well as a heat stabilizer in PVC. The list of products containing BPA is long. Some rigid containers such as water and baby bottles are made of PC. The popular NalgeneR water bottles are made of LexanR brand PC. In the medical industry, it is used for syringes, containers, lenses, and dental products. Keep in mind that the FDA regulates only plastics in contact with foods and not any of the other exposures a person might commonly experience every day at home, school, or the office. Because the FDA approves plastics for specific uses rather than for individual chemicals, BPA is not explicitly regulated. {20} It is important to note that all exposures, no matter what origin, are relevant and cumulative. Even other chemicals that act in the body in similar ways can be part of the total effect. The body's natural defenses try to break down toxins as they enter. These are called metabolites and can be significantly more toxic than the original chemical.

Today it is common that dentists coat children's teeth with dental sealants {21} that harden (polymerize) within the mouth. This exposure to BPA is large enough to have biologic effects. {22} Just as with other plastics, dental sealants polymerize imperfectly, leaving free monomers to be ingested or absorbed through the skin within the mouth. When it comes to dental solutions without plastic, the choices are limited. And I must say that I am extremely frustrated by the situation. One orthodontist I spoke with creates retainers from metal wire that can replace the standard polycarbonate ones. In tooth replacement, even some materials that dentists call ceramic have a polymer matrix. Gold caps or crowns are an excellent choice, but they too are glued into place with a volatile polymer. By far, the best alternative is to keep your teeth healthy by brushing and flossing regularly, and by eating a healthy diet.

Food and beverages cans are coated with a BPA-containing plastic. During the processing of canned food, it is sterilized in the can at 250 degrees fahrenheit for one hour. Because heat increases its migration, this is an especially large exposure for people who eat canned foods. As PC plastics grow old, BPA and other chemicals are released. But even when they are new BPA migrates out of PC plastic.

The Code of Federal Regulations section on PC plastics allows for migratory chemicals in the hundreds of parts-per-million (ppm) range as well as a percentage of the plastic's total weight. While concentrations of ppm and higher are relevant, there is vast area of exposure that falls well below the FDA's radar in the parts-per-trillion (ppt) range and lower. Testing methods are available, but the cost would be far greater. Because the industry is responsible for testing, it protests madly about the idea that these concentrations are relevant. If the table was turned and the burden of proof was on the consumer, the FDA would demand the most up to date testing methods. A graphic example of 1 ppt is one drop of liquid in 660 rail tank cars. That's a train 6 miles long!

In the year 2000, Consumers Union (CU) tested water from five-gallon PC plastic bottles for BPA, They found from 0.5 ppb to 11 ppb in water samples from eight of the ten 5-gallon jugs. {23} After industry spin-meisters discredited the study as being flawed, not many regulatory red flares were sent up within the FDA. This type of industry disinformation is standard operating procedure. Most times, the statements made could be compared it to one child calling another derogatory names, hoping that the recipient will become persona non grata with the other children. However, the CU study was indeed valid and the concentrations of BPA that were found are extremely relevant.

CU also found BPA in samples from baby bottles at worrisome levels. {24} CU advised its readers to avoid exposure to BPA by "dispos[ing] of polycarbonate baby bottles and replac[ing] them with bottles made of glass or polyethylene, an opaque, less-shiny plastic that does not leach bisphenol-A". {25} That advice attracted the wrath of the plastics industry. But I will go further and advise readers not to serve or store any food - liquid or solid, water-based or fatty, hot or cold - in any plastic.

In April 2003, a study was published about BPA accidentally killing mice that had been held in polycarbonate cages at a lab. {26} It was found accidentally when it ruined a lab experiment that heated yeast in PC flasks to find out if the yeast produced estrogens. It was discovered that BPA from the PC flasks was the material that was estrogenic, and that it competed with the natural estrogen in a rat's body. {27} I asked one noted researcher why labs still use plastics considering what it has been known since 1993 that BPA migrates and is hormonally active. The response was, "What are we supposed to do, go back to glass?" The tone of voice made it seem as if I had advised going back in time to live in the Stone Age. This is the state of what is still amazingly called science. There is a lack of reason and logic that goes well beyond what I knew possible before I began looking at the many aspects of this technology. Truth is sought, but the obvious is knocked to the ground and trampled over in the stampede to secure funding.

## **BPA's Rap Sheet**

The list of negative health effects associated in some way with exposure to BPA is remarkably long. The most visible effect may be aneuploidy, a chromosome abnormality found in more than five percent of pregnancies. Most aneuploid fetuses die in utero. About one-third of all miscarriages are aneuploid, making it the leading known cause of pregnancy loss. Among conceptions that survive to term, aneuploidy is the leading genetic cause of developmental disabilities and mental retardation. About one in 300 liveborn infants and one in three miscarriages are aneuploid. It is associated with Down syndrome {28}, Patau syndrome {29}, Edwards syndrome {30}, Klinefelter syndrome {31}, Turner syndrome {32,} Cri du chat syndrome {33}, and Alzheimer's disease {34}. And each of these bears its own extensive list of maladies covering all parts and functions of the human body - both physical and mental. The condition at birth is directly related to the type of chromosome abnormality present in the embryo at the time of conception. {35} It is well documented that aneuploidy contributes to the increased risk of spontaneous abortion when the female partner is older, but it is also thought that males more than thirty years old may increase the risk of spontaneous abortion when the female partner is less than thirty years of age. {36}

Being one of many known endocrine disruptors, BPA affects development, intelligence, memory, learning, and behavior, skeleton, body size and shape, significant increase in prostate size, decreased epididymal weight and a longer anogenital distance {37}, prostate cancer {38}, reduced sperm count {39}, both physical and mental aspects of sexuality. It may have something to do with obesity {40}, and so many more that a separate article is required to list them all. In other words, if the fetus lives, any one or many parts of its body can be permanently affected. The problems may become evident at any age.

Alzheimer's disease generally occurs after the age of fifty. In those afflicted with it, areas of brain become smaller with cell death and the cavities left become enlarged. The areas most affected are control memory, logical thinking, and personality. Only five to ten percent of the cases are inherited. Fourteen million people with Alzheimer's disease are predicted by 2050.

BPA is about 10,000-fold less potent than 17s-estradiol, a potent estrogen that is synthesized primarily in the ovary, but also in the placenta, testis and possibly adrenal cortex. Because of the disparity, industry representatives claim it causes no harm at the levels that the majority of people are exposed to. However, a study in 2001 showed that even at such low potency, when combined with other xenoestrogens (estrogens from outside the body), they act together additively, effectively raising the body load of estrogen to dangerous levels. {41} Another study showed that there is an increased sensitivity to BPA during the perinatal period, which begins with completion of the twentieth to twenty-eighth week of gestation and ends seven to 28 days after birth. {42} Exposure to BPA increases risk of mammary tumors. {43} To reiterate, there is no shortage of research published on the negative health effects of BPA.

## **Avoiding Plastic**

While it's impossible to avoid all plastics, we must rid our diets and lives of this toxic material as much as possible. There is a huge amount of data confirming the migration of plastic monomers and additives in all steps of food processing. {44} And in my opinion and that of many top research scientists, it is only a matter of time and money spent on new studies before the harm is found. Because of corporate political campaign financing, meaningful regulations resulting from studies will take even longer to become law. We must protect our families while the obvious results trickle in.

I strongly advise individuals and governments to ban plastics wherever possible by utilizing the precautionary principal. The Wingspread Statement on the Precautionary Principle is the consensus statement of a conference in 1998. Simply put it states that if you have reasonable suspicion of harm coming from (plastic in this case) then you must stop it from happening; the burden of proof must be on industry, not consumers; alternatives must be fully explored before using a new material or technology; and any decisions regarding such activities must be "open, informed, and democratic" and "must include affected parties". {45}

Evidence of the negative health effects of plastics already exists in sufficient quantity to halt the use of it in contact with food. More importantly, I feel that the manufacture of plastic itself must be halted for a multitude of reasons. Besides causing an endless number of human deaths, disabilities, and diseases, plastic is clogging all habitats of the world and destroying the ecosystem. There is now six times more plastic than plankton floating around in the middle of

the Pacific Ocean. Plankton is a major food source for sea animals. {46} A large portion of it is preconsumer plastic that has not been made into a product yet. Called nurdels, they look very much like plankton in size and color. According to a paper by Arrigo et al in Geophysical Research Letters in October 2003, plankton production has been declining for the last twenty years with rising ocean surface temperatures. Along with increasing plastic quantities, the ratio of plastic to plankton is increasing, making it more of a target for hungry animals.

The researcher who found this, Captain Charles Moore, Director of the Algalita Marine Research Foundation, told me that new data indicate that the ratio of plastic to zooplankton is even higher in two so-called floating plastic "Garbage Patches" that are each bigger than the State of Texas. {47, 48}

Nurdles are incorporated into all strata of the oceans with no known method of removal. DDE, a metabolite of DDT, and other dioxin-like chemicals concentrate on the surface of the plastic nurdles at a rate up to a million times that found in the ocean. {49} Captain Moore's presentation includes images of sea animals that have suffocated and starved as a result. Even more startling is seeing plastic bits incorporated into the flesh of the sea animals.

#### Conclusion

I spent about two years answering telephone inquiries at an environmental organization in Berkeley. A great number of the callers asked what the safest plastic to use in contact with food or water is. They also wanted to know what the safest plastic is to microwave food in. My answer was that plastic should never contact food. And that one should never microwave food it's probably as bad or worse than putting it in plastic because it creates free radicals in the food that damage cells in your body. It also heats the plastic, thus increasing the rate of migration into the food. That answer wasn't popular with either the caller or the organization, which likes to point out positive alternatives. However, plastic is the alternative! And glass, wood, metal, and ceramics are the real things. Plastic is merely a foul imitation thereof. By using the least offensive plastic, one only prolongs and increases the toxic load on the Earth and in our bodies. If saving trees is your aim, stop using so much stuff. But in the mean time, don't further degrade the environment with more plastic.

As consumers, we always look for ways to maintain the status quo of our modern lives. However, the only logic I can see in the regulation of food contact plastics is profit at the expense of our health, the economy, society, and environment. You needn't be a polymer scientist to know that plastic shouldn't contact food. What is essential though is a firm standing in reality and a good grip on logic. It also requires being free of ties to the industry before that logic becomes evident.

First set aside your assumptions and look at the known long- and short-term negative effects of plastic on health, economy, environment, and society, as well as the long-term viability of the human race. Next contrast that with what you find as benefits. I guarantee that the stack of chips will be far larger in the negative pile.

## Further Reading

Alternatives to Plastic Paul Goettlich (August 03 2005)

78 Reasonable Questions to Ask about Any Technology - Stephanie Mills / Clamor, i.18, Jan/Feb03

Identification Of Volatile Organic Compounds In a New Automobile - Scientific Instrument Services 23dec99

EDSTAC Review - Davis Baltz / Commonweal 6may00

Middlesex and the Limitations of Myth - Thea Hillman / ISNA News Spring03

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- {2} Guidance for Industry: Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations FINAL GUIDANCE US Food and Drug Administration, Center for Food Safety & Applied Nutrition, Office of Food Additive Safety April 2002

  http://www.cfsan.fda.gov/~dms/opa2pmnc.html
- {3} Telephone conversation with Dr George Pauli, Associate Director of Science Policy, FDA Office of Food Additive Safety, and Mike Herndon, Head of Media, FDA Office of Food Additive Safety 22 October 2003 12:49 PM
- {4} Polyethylene (source FDA telephone conversation)
- {5} Cladosporium: Ascomycete. The most common mold in the world, found in soil and on textiles, tomatoes, spinach, bananas, and dead vegetation. For image <a href="http://www.carolinafilters.com/FunclspP.jpg">http://www.carolinafilters.com/FunclspP.jpg</a>
- {6} Fungicides are a category of pesticide as regulated by the EPA. See What is a Pesticide? US EPA Office of Pesticide Programs 14feb97 <a href="http://www.mindfully.org/Pesticide/What-Is-A-Pesticide.htm">http://www.mindfully.org/Pesticide/What-Is-A-Pesticide.htm</a>
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- {10} Barbie's PVC Body Gets Sticky as Dibutyl Phthalate Migrates Yvonne Shashoua / Conservation Department The National Museum of Denmark 19apr99 <a href="http://www.mindfully.org/Plastic/Barbies-Health-Hazard.htm">http://www.mindfully.org/Plastic/Barbies-Health-Hazard.htm</a>
- {11} Paracelsus: Dose Response. in the Handbook of Pesticide Toxicology WILLIAM C KRIEGER / Academic Press Oct01. Robert Krieger, ed. University of California, Riverside, Riverside, California, USA. <a href="http://www.mindfully.org/Pesticide/Paracelsus-Dose-ToxicologyOct01.htm">http://www.mindfully.org/Pesticide/Paracelsus-Dose-ToxicologyOct01.htm</a>
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- {13} What Are Endocrine Disruptors? Paul Goettlich 2jul03 http://www.mindfully.org/Pesticide/EDs-PWG-16jun01.htm
- {14} Telephone conversation with Ernest Sternglass, PhD, Professor Emeritus of Radiological Physics at the University of Pittsburgh Medical School has written numerous articles on the health effects of low-level radiation. He is Director and Chief Technical Officer of the RPHP Baby Teeth Study <a href="http://www.rphp.org">http://www.rphp.org</a>
- {15} Leuren Moret Speaking on Depleted Uranium in Los Altos, California 21apr03 <a href="http://www.mindfully.org/Nucs/2003/DU-Leuren-Moret21apr03.htm">http://www.mindfully.org/Nucs/2003/DU-Leuren-Moret21apr03.htm</a>
- {16} As evidenced by strontium-90 being detected by the Tooth Fairy Project in many thousands of baby teeth http://www.radiation.org/envelope.html
- {17} CAS Registry Numbers for new compounds and assistance with nomenclature can be obtained by writing to Chemical Abstracts Service (CAS) Client Services, 2540 Olentangy River Road, P.O. Box 3343, Columbus, OH 43210, or by visiting their website at <a href="http://www.cas.org">http://www.cas.org</a>
- {18} Today's date: 9 October 2003
- {19} Formula:  $2^n n 1$  This is called a factorial. Dr Bruce Sagan, amathematician at Michigan State University, did the calculation. Example: where  $2^n$  means 2 to the power n. So, for example, when n = 10 then there are  $2^10 10 1 = 1024 11 = 1013$ . This formula accounts for duplications such as 1,2,3 = 1,3,2 = 2,3,1 = 2,1,3 = 3,1,2 = 3,2,1 {20} 21 CFR  $3^n$  SB! $3^n$  Code of Federal Regulations rev.1apr03 http://www.mindfully.org/Plastic/PC/21CFR177.1580-Polycarbonate-1apr03.htm

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