LEAD CONTENT OF SOIL, PLANTS, FOODS, AIR, AND CHINESE HERB FORMULAS

LEAD AND ITS NATURAL DISTRIBUTION ON EARTH

There are growing concerns about lead because it is the heaviest of the non-radioactive metals (atomic number 82; atomic weight 207) that naturally occur in substantial quantities in the earth’s surface. Lead is present in all soils, rivers, lakes, and seawater. Despite its weight, lead is also in the air, a component of dust and of sea spray. Lead is present in the proportion of 16 parts per million (ppm) in igneous rocks, the most common ancient rock on the surface, and at an average of about 10 ppm in common soils that are far from sites of contamination; natural soils usually have less than 50 ppm of lead but are never lead free.

In controlled drinking water, the level of lead is currently limited in the U.S. to 0.015 ppm (0.01 in California), which is still slightly above the naturally occurring levels; that is, there is still contamination from human activities. The adult human body contains lead equivalent to about 2 ppm (range: 1.4-5.7 ppm) for the entire body weight, with about 90% of it concentrated in the mineralized portion of the body, the bones, at 20-40 ppm. Lead enters the body from the air during breathing, but most of it is taken in orally, where it is a component of food, beverages, drugs, supplements, and almost anything else that is ingested. A total daily lead exposure (inhaled and consumed lead) of 0.5 mg per day of lead appears normal in a relatively clean environment today.

THE SPRAYING OF EARTH WITH LEAD

Although humans have mined and worked with lead for more than 2,500 years, this activity became massive during the 20th Century; as a result of the way in which lead had been used in recent decades, the earth was coated in a fine layer of lead. The more than 300 million tons of lead that was pulled out of mines from 1920-2000 was distributed into the air via combustion activities or applied as a thick coating to surfaces in the form of leaded paint. Lead was introduced directly into water supplies via lead in water pipes and into food by using lead in cans (called “tin cans” but made of steel soldered at the seam with a lead compound), pottery, and glassware.

The most serious worldwide lead contamination has been due to the introduction of lead (in the form of tetraethyl and tetramethyl lead) into gasoline, starting in 1923, with billions of tons of lead released into the atmosphere in the vehicle exhaust. Most of the discharged lead lands on the soil, in the water, and on living organisms, particularly the plants that grow along the roadways. Although lead was phased out of gasoline in the U.S. in 1971, leaded gasoline is still being used in many countries, most notably in Africa. In Europe, the lead content of gasoline has been gradually reduced, but not eliminated. Leaded gasoline has been phased out in Austria, Denmark, Finland, Sweden and Switzerland, and restricted to a maximum 0.15 grams/liter (about 150 ppm) in most countries, compared to earlier levels that were up to five times that amount (750 ppm, with reductions to 320 ppm in the mid-1990s). China announced its intention to eliminate lead from gasoline at the end of 1999, limiting the average lead content of gasoline to 0.005 grams/liter (5 ppm, similar to the content of unleaded gasoline). The 5 ppm standard has been adopted recently by several other countries as well.

Even when lead additives are removed from gasoline, smaller amounts of lead continue to be emitted from automobiles, trucks, and other vehicles. In addition to some natural lead in gasoline, the gradual loss of
The main health problems associated with chronic high levels of lead in the blood are neurological impairment in children (including possible permanent damage if exposed to high levels at an early age) and hypertension in adults. Children’s blood levels should be no higher than 6 µg/dl to avoid subtle neurological symptoms (above 10 µg/dl the symptoms can become evident) and adult levels should be no higher than 25 µg/dl to avoid hypertensive symptoms (above 30 µg/dl a mild hypertensive effect has been noted in males). Pregnant women must be especially cautious about lead exposure, both because of increased risk of spontaneous abortion and potential damage to the fetus, which could occur with maternal blood lead levels of 10 µg/dl or more. Other possible health problems due to lead exposure at low levels have been proposed but remain controversial.

HEALTH PROBLEMS DETECTED

Children below the age of 5 represent a special concern for lead exposure because of the high frequency of putting various things in the mouth, including soil and items that have been on the floor, picking up dust and dirt. Normally this would not be a problem, but with lead contamination of the environment, especially from old crumbling house paints, it can be a strong component of childhood exposure, with soil and dust having 10 to 100 times, or higher, the concentration of lead as found in food. Paint contamination of house dust and of soil surrounding houses was one of the primary factors that led to awareness of the need to control human exposure to lead in the U.S. In 1970, over 2,000 children under 6 years of age in New York City alone were treated for lead poisoning, due primarily to lead paint, and this clearly demonstrated the need to reduce all major sources of lead exposure, with a focus on the most widespread source: gasoline. In Germany, the primary reason for instituting control of lead emissions from gasoline was the evident destruction of the forests along roadways.

CLEANING UP LEAD IN THE ENVIRONMENT

With increased understanding of the potential dangers of lead exposure, the environment in the U.S. and most other countries is being slowly being cleared of lead contamination. Dangerous levels of lead are mostly confined to the areas around mines, manufacturing facilities that still deal with lead (such as lead used for batteries and ammunition, and metal recycling plants), old city lands, landfills and facilities contaminated from years of earlier exposure, and cities in developing countries that still use leaded gasoline.

In the U.S., lead emissions into the air declined from 221,000 tons in 1970 (after which all new cars had to use unleaded gasoline), to 160,000 tons in 1975, 74,000 tons in 1980, and down to 4,000-5,000 tons per year during the 1990s. In 1998, the most recent year with published data (Statistical Abstracts of the U.S.), the lead emissions in the U.S. were just under 4,000 tons. This dramatic decline shows the huge influence that leaded gasoline had; the remainder of emissions today is mostly due to industrial discharge of lead (metals processing accounts for more than half of the current U.S. lead emissions) and small amounts from non-automotive fuel combustion. The reduction of lead in gasoline results in substantial declines in blood lead levels. In Germany, several studies have been conducted to monitor these levels. During the mid-1970s the blood levels were averaging about 12-13 µg/dl, which is today considered a toxic level for children (for adults, blood lead has been considered normal in city dwellers when below 25 µg/dl). By the mid-1980s, the lead content of blood in Germans had dropped to 6-8 µg/dl, which is today regarded as a common non-toxic level. By the mid-1990s the blood levels in Germany had declined to 4-5 µg/dl. U.S. blood levels have already declined to the range of 2-4 µg/dl. Based on studies of pre-Columbian bones, it has been estimated that natural blood lead levels in America were once less than 1/10 the current levels.

The FDA presented data on changes in lead content of infant formulas from the early 1970s (when lead had just been deleted from gasoline) to the mid-1980’s. The content of infant formula, infant juice pro-ducts, and infant foods declined from 0.1-0.3 ppm to 0.01 ppm, a 10-30 fold decline; lead in evaporated milk declined from 0.5 ppm to 0.01 ppm, a 50-fold decline. Removal of lead solder from cans resulted in a decline in lead content of canned foods from an average of 0.2 ppm to an average of 0.1 ppm for adult foods and to 0.04 ppm for children’s foods. Clearly, the lead in foods can be reduced to low levels with sufficient efforts to minimize contamination. Most commercial lead tests can only detect 0.25-0.5 ppm, so these food levels fall below commercial testing levels. For adults who consume foods with an average lead level of 0.1 ppm, a kg of food (about the daily amount consumed) will yield only 0.1 mg of lead.

The World Health Organization has
established a “tolerable weekly intake” level for lead at 1.5 mg, corresponding to a daily lead intake of just over 0.2 mg (200 µg). This is a goal that is not yet attained in many parts of the world, but may be consistent with what is possible after removal of all intentionally-added lead from gasoline, water pipes, and food cans. An even lower intake level has been proposed for future consideration as follows: 6 µg/day for children up to the age of 6 years, 15 µg/day for children 7 years of age and older, 25 µg/day for pregnant women, and 75 µg/day for all other adults.

When discharge of lead into the atmosphere declines, lead is slowly removed from the biosphere. An increasing proportion of the circulated lead becomes trapped in compounds that poorly absorbed by living organisms. While the lead remains at the earth’s surface and in seawater, the amount entering into plants and animals declines rapidly. Thus, for example, the amount of lead permitted in drinking water in California declined from 0.05 ppm to 0.01 ppm as the environment became cleaner and permitted imposition of the more stringent standard that is now met.

Lead from the atmosphere that lands on soils has low mobility and tends to stay in the top inch of soil. Therefore, shallow-rooted plants, such as grasses and common vegetables, are particularly vulnerable to picking up lead contamination that originated in the atmosphere. One of the main dietary sources of lead is from grains (a type of grass), and whole grains are particularly high since the fibrous seed coat retains minerals; the second main dietary source of lead is vegetables; meats are usually third.

Lead also enters seawater and, from there, sea plants and animals. Marine organisms concentrate lead relative to that in seawater by a factor of 100-300 times, but the lead content of seawater is low, so the concentration of lead in edible sea foods is still low. In a study of fish used as food sources the lead content was found to range from 0.004-0.050 ppm, a trivial amount. Shellfish concentrate minerals, including lead, into the shells, which are usually not eaten (however, oyster shell is used as a dietary supplement and antacid and an ingredient in Chinese medicine formulas; see Appendix 1).

The human body eliminates lead via many mechanisms. Lead exits the body via: feces (mainly as the result of dietary lead not being absorbed, but also discharged via the gallbladder from breakdown of hemoglobin that binds lead); through sweat; excretion into the skin, hair, and nails; and through the urine and the breath. Except at times of unusually high lead exposure, the total lead taken into the body each day is eliminated each day. A certain relatively constant level of lead remains in circulation in the blood; small amounts are also present in all the soft tissues and larger amounts are present in the bones; the levels depend on the average daily exposure to lead.

Estimates of human daily lead consumption from food, water, and other sources is on the order of 1-2 mg/day at present in countries that control lead emissions, compared to about 3-6 mg/day (or more) in 1970. Lead in drinking water is no longer a significant source, but it had contributed about 0.5 mg/day in the 1970s. In one evaluation of data from 1980 the pattern of lead exposure was illustrated (in Americans; typical contributions): solid foods, 1.2 mg; beverages, 0.03 mg; public water, 0.2 mg; air intake, 0.225 mg; for a total lead intake 1.655 mg. Smoking cigarettes can contribute 500 µg each by inhalation, one pack providing 1 mg of lead; the amount retained by the body is not established (some is exhaled immediately with the smoke).

According to an FDA report (mainly relying on EPA data), by the mid-to late- 1980s, ingestion of lead in the absence of cigarette smoking had diminished to microgram levels, one tenth that previously reported for adult daily lead exposures. The figures given were: food 9-10 µg; indoor air 0.17 µg; outdoor air 0.55 µg; street dust 0.11 µg; house dust 5.3 µg; for a total of just 15-16 µg/day. In a study of young
American children, it was reported that the national estimate for total dietary intake is 1.4 µg/day (1/7 the adult exposure), but that in children living in environments contaminated with lead, the daily intake was 29 µg (20 times higher). The foods could become contaminated in these environments with impure water used in preparation and by dust and dirt that contained high levels of lead.

In a study of dietary lead intake in Spain, the daily levels reported ranged from 37 µg to 521 µg (the latter in Madrid, almost all of the excess due to contaminated cereals). The authors compared these values to those that had been reported in other countries, namely Sweden (17 µg), the Netherlands (32 µg), Belgium (179 µg) and Italy (280 µg). All these values are considerably higher than the 9-10 µg indicated by the EPA for the U.S. Other estimates for American dietary intake suggest 250-350 µg per day; the marked difference is no doubt due due several factors, including differing test methods, population selection, dietary components evaluated, and year of testing. It is likely that the lead levels have declined since these reports as a result of implementing the earlier lead-reduction policies.

New regulations are being established to have maximum food lead levels at a significantly lower range than was found during the 1990s. For example, in Rumania, food products are limited to 0.1 to 0.5 ppm of lead (the limit assigned is dependent on the food), and most foods sampled met these standards or nearly met them (the highest measured being certain cheeses at 0.7–0.8 ppm rather than 0.5 ppm). In Europe, proposed standards included 0.1–0.3 ppm for fruits; 0.2 ppm for fish; 0.05 ppm for meats (cattle, sheep, pigs) and for juices. In the U.S., current lead levels in foods are in the range of 0.1–0.3 ppm (in beverages they are 0.02–0.03 ppm) and, thus, meet these proposed standards. Farmers have limited ability to control conditions that affect the lead level of foods they produce; rather, government policies limiting lead in gasoline, water, and industrial discharge can result in lower lead content of agricultural produce. Should one expect herb products and other supplements to meet a similar limitation on lead levels?

The lead limit for pharmaceutical products, according to the U.S. Pharmacopoeia, is 10 ppm, and this figure is cited by U.S. test labs as the acceptable limit for herb products, dietary supplements, and drugs. More than 90% of the Chinese patents meet this standard. In fact, most patents tested had less than 3 ppm of lead (generally less than 2 ppm). The question arises: where does the lead in the patents come from? Suggestions made by various writers on the subject included: growing herbs in highly contaminated soils; applying pesticides or fumigants that contained lead; manufacturing products in contaminated facilities; and using lead-containing mineral compounds in the formulation.

In fact, Chinese herbs are collected in vast quantities and necessarily come from rural areas. While these areas are not assured of being free of high levels of lead contamination, they are gene-rally away from industrial and mining areas, and, therefore are not likely to pick up high levels of contamination from the soil and air. The overall air quality in China is poor, due largely to extensive burning of coal, which contributes lead dust. In one Taiwanese study, the highest lead level detected in 17 medicinal materials from plants was 20 ppm. Still, tests of plants growing in contaminated soils in a city indicate that they usually do not have lead concentrations higher than 10 ppm, and tend to have lead levels below 1 ppm (see Appendix 2).

Pesticides and fumigants are used for some Chinese herbs that are cultivated, but are used sparingly due to their costs, and such contaminants rarely show up on testing. While metallic agents are used in some pesticides and fumigants, lead is not an ingredient that is known to be helpful for the intended purpose and is unlikely to become a significant contaminant from pest control applications.
Tests of U.S. manufactured products, made primarily from herbs imported via Hong Kong, show moderate lead levels, typically below 2 ppm (see next section), indicating that the herb materials themselves are not highly contaminated. The lead must be coming primarily from the activities in the manufacturing facilities and/or the particular selection of ingredients used in the products made in China.

Chinese manufacturing facilities vary markedly in quality from one to another, but many of the items that come to the U.S. today are from famous factories that have a major investment in quality control, including avoidance of any overt contamination. However, polluted water used in processing herbs (such as making extracts by cooking in water and then drying the resulting liquid) will concentrate lead and other contaminants into the finished herb product. The factories are often located in major cities, where the water supply in the past may not have been regulated for lead contamination. Most of the products tested were manufactured in the early 1990’s, before China began imposing appropriate environmental controls.

Although many patent pills are made from powdered herbs, which would have the same lead concentration as the crude herbs, several patent pills are made from dried hot water extracts. These extracts are made by boiling the herbs in water, just as one would do to make a decoction, and then drying the extract. Most of the lead in the plant or animal materials will be concentrated (some will be left behind in the drogs) and virtually all the lead contained in the water used for making the extract will remain in the finished product. Together, the herb extracts and the water in a concentrated product might explain the lead content of pills that reach 2-3 ppm. Still, such processes cannot readily explain the products that had more than 3 ppm of lead. For those, it is necessary to consider other sources.

**INTENTIONAL ADDITION OF LEAD-CONTAINING MATERIALS**

Throughout the history of Chinese medicine, mineral substances have played an important role, and particularly in the manufacture of pill products. One of the more famous mineral medicines is Purple Snow Pills (Zi Xue Dan). The formula includes talc, gypsum, calcite, magnetite, niter, and cinnabar, combined with several herbs. None of these minerals are lead compounds, though they can have small amounts of lead with them, as would be found in virtually anything mined from the earth. In the California FDA test of Zi Xue Dan from Guangzhou, the results indicated a lead content of just 3 ppm; this is a normal to low level of lead to be found in minerals (niter and cinnabar would be expected to have low lead; the others somewhat higher, particularly magnetite, an iron compound).

There are some lead compounds that may be rarely used in Chinese patent pills that contribute to high lead levels. The main ingredients of concern are minimum (qiandan) and litharge (fenxi; mituoseng), which are mainly lead (see Figures 1 and 2 for illustration of their traditional processing). These are sometimes used in formulas for children because they are reputed to calm fright, remove phlegm, relieve convulsions (e.g., epilepsy or convulsions due to fever), and kill intestinal parasites—major areas of concern for children. Minium was originally an ingredient of the famous Shang Han Lun prescription Bupleurum and Dragon Bone Combination (Chaihu Longgu Jia Muli Tang), a formula for mental distress secondary to a feverish disease. In recent decades, it has been removed from the formula due to concerns about lead toxicity.

Litharge was traditionally used to treat dysentery in small children. It was reported in Hong Kong that a patent remedy commonly prescribed to children, Bao Ying Dan, can sometimes have high lead levels. In one instance, an herbal powder provided to an infant in Hong Kong contained 23% lead by weight.

When lead compounds are intentionally added to some formulas, there can be residues of lead in equipment used to make the products that will then contribute to lead in other products. For example, in a few patents tested by the California FDA, lead content was in excess of 100 ppm, probably due to intentional addition of mineral compounds containing lead. If only a tiny amount of the lead compound added to such pills contaminates a different batch of product not intended to include lead, it could easily raise the lead content of that batch by a measurable quantity.

Also, throughout the history of Chinese medicine, animal products have played an important role. These are often used in pill form because they are typically rare and expensive and when boiled in a tea may leave behind most of their active components in a gummy residue. In particular, calcified materials are often used by the Chinese, such as antlers, horns, bones, gallstones, and shells. Living organisms generally will concentrate lead into calcified substances. Several of the patent medicines tested in California that have high concentrations of lead contain calcified animal substances. One of the most highly contaminated of the patents, in terms of lead, are Double Dragon Pills manufactured in Hong Kong. The ingredients listed on the package, which are no doubt not the complete set, include pipefish, seahorse, tiger bone gelatin, cow bone gelatin, harts horn, and other animal ingredients. These pills did not test positive for mercury or arsenic. If lead was present in the bones and horns at a concentration of 20-40 ppm, a four to one concentrate would raise the lead level to 80-160 ppm, contributing to the excessive levels detected, but not explaining the greater than 300 ppm of lead reported.
Fortunately, whatever lead compounds are contaminating some of the Chinese patents manufactured in Hong Kong (and more rarely in mainland China), the same problem is not being found in the formulas manufactured in the U.S. This is likely due to three factors: the selection of ingredients in which lead and other heavy metals are not prevalent; manufacturing facilities that are free of lead contamination; and the use of clean water in making extracts. ITM has had a dozen formulas tested, most of them selected with the expectation of having somewhat elevated lead due to incorporation of mineral compounds. The results are presented here: Some of the tests were conducted with a limit of detection of 0.5 ppm, others with a limit of 0.25 ppm; of the latter, the lowest lead level detected was for Restorative Tablets at 0.3 ppm. ITM asked its supplier to check the oyster shell used in making Seven Forests products, since the oysters are cultivated at the Chinese coast and could easily be contaminated. The laboratory report showed only 1.3 ppm, which is a reasonably low level (see App. 1). Tests of tortoise shell, tortoise shell gelatin, antler gelatin, dragon bone, and gypsum all showed less than 0.5 ppm of lead. Based on the test results for the complete formulas, it is very unlikely that any single ingredient within the formulas had more than 10 ppm of lead.

Two U.S. manufacturers relayed information that Chinese herb products they manufactured and tested had lead levels not exceeding 3 ppm, with many having not more than 1 ppm; this is consistent with the data presented above. Another U.S. manufacturer provided test data for 58 products, for which all but 3 had lead levels below the detection limit of 1 ppm, and the remaining 3 met the 10 ppm standard. Most American herb product distributors claim to conduct regular testing of their products for heavy metals, but have not publicized what they find. Therefore, additional details are not available for this report. However, with the very large number of commonly used herbs included in the products for which test data have been provided, it can be concluded that almost all the individual herb materials used to make the formulas have less than 3 ppm of lead in the crude dried herb.

When using herb products in the form of tablets, pills, and capsules, the daily dose of finished product recommended to be ingested is often less than 6 grams/day. At 3 ppm of lead, a level higher than that typically found in American made products and higher than that found in 70% of the patents tested by the California FDA, a person ingesting such products would obtain about 0.02 mg of lead (20 micrograms). Thus, lead in Chinese herb formulas (other than select items from Hong Kong that tested much higher than 3 ppm), should not be a health concern for the Western consumer. The WHO-recommended maximum daily exposure of 0.2 mg/day (200 micrograms) could easily be met when using such products (which provide up to 10% of the daily intake limit), as could the more stringent level of 75 µg per day proposed for the future. Virtually all manufacturers, distributors, and importers of herb products today are monitoring for heavy metal contamination to make sure that there is no excessive amount of lead or other metals of concern.

As the environment is cleaned of lead pollution, one should expect to have lower exposure to lead from herb products. It is proposed here that the herb industry should adopt a uniform maximum level of lead content for herb products and that the maximum allowable amount will decline over the next several years as the environment in China (and other source countries) is cleaned of its lead contamination. The current standard is the U.S. Pharmacopoeia level of 10 ppm. In a report published in Germany in 1978, it was suggested that herbal materials could comply with a standard imposed there in 1967 of 5 ppm of lead. A newer standard of just 1 ppm lead for 95% of samples was recommended in a 1998 report. However, certain herbs seemed to normally have higher lead levels, and exceptions were to be made as follows for maximum lead content: willow bark 3 ppm; frangula bark and sundew herb 7 ppm; ginkgo leaves 11 ppm, and Iceland moss 14 ppm. The high level for Iceland moss, which is really a lichen, can be explained by the fact that this species grows on rocks and is highly efficient at deriving minerals form them, including lead. The high level of lead in ginkgo leaves (these are grown in Europe) are likely the result of lead emissions from autos and industry, a problem which, as described above, is gradually being resolved.

It is proposed that the 10 ppm lead standard based on the U.S. pharmacopoeia for drugs, should be cut by about 1/3 for finished Chinese herb products for the year 2002, and again by 1/3 by the year 2007 (perhaps gradually, rather than a single reduction). During this 5-year interval, the environment will continue to become cleansed of the heavy lead pollution from the earlier decades, leaded pipes will be replaced and purified water used, and manufacturers will have more experience testing herb materials, being able to identify any items that have higher lead levels so as to avoid using them in the future. In terms of product safety, the proposed levels for 2002 should be adequate to meet virtually all known requirements.

### CONTRIBUTION OF HERB PRODUCTS TO DAILY LEAD INTAKE

<table>
<thead>
<tr>
<th>Formula Name</th>
<th>Lead Content (ppm)</th>
<th>Formula Ingredients Expected to Have Elevated Lead Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acorus Tablets</td>
<td>&lt; 0.5</td>
<td>oyster shell (6%)</td>
</tr>
<tr>
<td>Antler 8</td>
<td>&lt; 0.5</td>
<td>deer antler, antler gelatin (50%)</td>
</tr>
<tr>
<td>Chih-ko/Curcuma 1.0</td>
<td></td>
<td>arca shell, oyster shell, myrrh (20%)</td>
</tr>
<tr>
<td>Coix Tablets</td>
<td>&lt; 0.5</td>
<td>highly concentrated coix, a grain (14%)</td>
</tr>
<tr>
<td>Fu-shen 16</td>
<td>1.5</td>
<td>dragon bone, oyster shell, hematite, hematite (28%)</td>
</tr>
<tr>
<td>Ganoderma 18</td>
<td>&lt; 0.5</td>
<td>highly concentrated ganoderma (12%)</td>
</tr>
<tr>
<td>Laminaria 4</td>
<td>&lt; 0.5</td>
<td>oyster shell, pumice (20%)</td>
</tr>
<tr>
<td>Restorative Tablets</td>
<td>&lt; 0.5</td>
<td>tortoise shell (12%)</td>
</tr>
<tr>
<td>Salvia/Amber Tablets</td>
<td>&lt; 0.5</td>
<td>dragon tooth (13%)</td>
</tr>
</tbody>
</table>
SUMMARY

Lead contamination of the environment was a major problem during the last half of the 20th century and there are residual aspects of this problem, including continued use of leaded gasoline in many countries and persisting contamination of the surface soil. Chinese herb products have some level of contamination reflecting the lead taken up by plants and animals, but certain products appear to become significantly contaminated mainly during manufacture in China, particularly in Hong Kong. The excessive lead in those products may come from intentional addition of substances that have elevated lead levels, concentration of lead in the original materials by making dried extracts, and contribution of lead from contaminated water and contaminated facilities. Efforts are being made in China to reduce lead contamination, including cleaning up drinking water and eliminating lead in gasoline, as well as improving manufacturing procedures at the herb factories. One can expect the lead contamination of herbal materials to decline in the future. Although the lead content of American-made Chinese herb products and most imported Chinese herb products is not sufficient to contribute to any health problems, the lead content can be further limited by proper monitoring, correct manufacturing procedures, and avoidance of high lead substances in formulas. A timetable for reduction of lead levels in Chinese herb products has been proposed that is consistent with available data about current lead levels and reasonable expectations for reductions in the lead content of soil, water, plants and animals.

<table>
<thead>
<tr>
<th>Proposed Maximum Lead Levels for Finished Chinese Herb Formulas</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufactured By</strong></td>
</tr>
<tr>
<td>2001 and almost all imported Chinese herb formulas meet this standard (nearly 5% of California FDA tested Chinese imports did not).</td>
</tr>
<tr>
<td>2002-2006 maximum for any one ingredient</td>
</tr>
<tr>
<td>2007-2011 maximum any single ingredient; with listing of exceptions based on natural lead content</td>
</tr>
<tr>
<td>2012 and after 0.8 ppm total formula; 2.5 ppm maximum any single ingredient, with listing of exceptions for certain formulations and single ingredients</td>
</tr>
</tbody>
</table>

RESOURCES

The information and data conveyed in this article, other than that relating directly to lead content of herbs, was derived primarily from reports published on the internet and abstracts presented on the PubMed site (National Library of Medicine). Use of lead compounds in traditional Chinese medicines is relayed in Chinese Medicine: History of Pharmaceutics (1986 University of California Press, Berkeley, CA) and Introductory Readings in Classical Chinese Medicine (1988 Kluwer Academic Publishers, Dordrecht, Holland) both by Paul Unschuld, and in Oriental Materia Medica (1986 Oriental Healing Arts Institute, Long Beach, CA) by Hong-yen Hsu and his colleagues.

Data on lead levels in Chinese imported patents was published by the California Department of Health Services (1998), prepared under the direction of Richard Ko and Alice Au of the Food and Drug Branch. Cases of high-lead products used in Hong Kong for children were relayed by Paul PH But and WK Kan in an article in Abstracts of Chinese Medicine (1995; volume 6, #1). Lead content of European herbs was relayed in an article by Lothar Kabelitz in an article titled Heavy metals in herbal drugs in the European Journal of Herbal Medicine (1998; volume 4, #1). Data on Seven Forests herb tablets was provided by California test laboratories, Weber Laboratories, and A&L Western Agricultural Laboratories. Information relayed from other herb companies was by personal communication and remains confidential.
APPENDIX 1:
LEAD CONTENT IN CALCIUM SUPPLEMENTS, OYSTER SHELLS, AND BONES

In the Journal of the American Medical Association, September 20, 2000, was an article that presented test results of lead content in 23 products that contained high levels of calcium, either as nutritional supplements specifically intended to provide calcium or in antacids (the latter have been promoted as having the benefit of a nutritional supplement). With one exception, the calcium in all the products is in the form of calcium carbonate. A common source for calcium carbonate for such supplements is oyster shell, which was the source noted for some products, though others did not mention the source material. More than half the products (14 of them) had lead levels below the detection range (0.25 ppm). The others (9 products) had lead content ranging from 0.35 ppm to 0.81 ppm. These tests reveal that calcium materials can have about 1 ppm of lead or less (note: not all of the tablet material is calcium carbonate, but the tests were on the complete tablet, so the calcium carbonate portion would have a higher lead content than the finished tablet).

A supply company for oyster shell (Micro Powders and Braig, Inc.) claims to mine buried ancient oyster shell material that was deposited long before humans contaminated the world with excess lead. The shells are from under San Francisco Bay and are said to be carbon dated to 2000 years ago. They are carefully washed of current marine sediment and said to have a lead content less than 0.4 ppm. The suggestion is that natural lead content of oyster shell is below 0.4 ppm and that the higher levels (about 1-1.5 ppm) often seen now are the result of lead pollution of the offshore seawater. Although buried oyster shell beds may undergo changes that could include leaching of lead, the level of 0.4 ppm seems reasonable given the current range of oyster shell lead levels.

There is some evidence from human bones as a means of monitoring changes in the environmental lead levels. Modern human bones will often have 20-40 ppm of lead, while bones of Native Americans that are about 1,500 years old have lead levels of about 4 ppm (5 to 10 times less). Bones of ducks have been tested and found to sometimes exceed 20 ppm, the elevated levels attributed to their eating of lead shot left by duck hunters (in some areas where ducks and geese congregate, 12,000 lead shots per acre were found). The potential for harm from lead ingested in calcium compounds (such as calcium carbonates) may be overstated. Calcium blocks the absorption of lead from the intestinal tract and calcium reduces the toxic effects of lead. Therefore, when lead is present in small amounts in compounds rich in calcium, its contribution to blood lead levels may be entirely negated by the calcium.

APPENDIX 2:
LEAD CONTENT OF SOILS AND PLANTS

In a study of soils in the New Orleans area, the concentration was found to be in the range of 30-50 ppm except at a site with a very high traffic area, where the lead concentration was 300 ppm. A variety of plants were tested in these areas. Except for one sample of grasses that had high lead content (7.5 ppm), all the plants had from 0.4-4 ppm of lead in their dried material. In rural areas, grass still had a relatively high lead content, but much lower than in the urban zone, with only 0.9 ppm, while the other plants in the rural area all had less than 0.1 ppm. This study confirms that high-traffic city areas have had, at least in the past, substantially more lead in the soil than rural areas and that plants are capable of absorbing extra lead; some plants, in this case a grass species, naturally absorb far more lead than others. This study also shows that it is reasonable to expect herbs to contain less than 8 ppm lead in their dried form even when grown in city soil and less than 1 ppm in rural soil. Thus, a standard of 1 ppm of lead for an herbal formula (proposed for 2007) should be attainable so long as herbs are grown and collected away from polluted areas. However, as indicated above, when herbs are concentrated the lead content of the finished product can be expected proportionately.

A study of correlation between lead in soil and lead in blood serum showed that when the soil content of lead exceeded about 500 ppm (50 times the average for normal soil), it could affect children’s blood lead levels. Much of this effect came from young children (below age 5) getting soil in their mouths while playing, the soil being contaminated by outdoor leaded paints chipping off buildings, discharge from motor vehicles, and industrial pollution. In several countries, lead standards have been adopted for residential land use. Generally, a maximum soil concentration of 500 ppm has been adopted. In Canada, a lower level of 375 ppm was adopted for sandy soils only.

APPENDIX 3:
LEAD IN THE AIR

Lead content in the air has been declining with efforts to remove it from gasoline, but it continues to be a pollutant from several sources, including industrial activity and continued use of leaded gas in some countries. The highest concentrations are found near lead smelters and along urban freeways where leaded gas is used, with typical levels of more than 10 µg/m³. Aside from those extremely elevated levels concentrated locally, about a 10-fold range of air levels has been measured among various cities and adjacent rural areas. For example, the Tokyo/Kyoto area had an atmospheric lead content of 0.075 µg/m³, whereas the contaminated city of Manila had 9 times as much: 0.650 µg/m³. In one study of lead content of American air during the 1980s, it was reported that it ranged from 0.3-1.1 µg/m³ in urban areas, but one half to one third that amount in surrounding rural areas: 0.15-0.30 µg/m³ and less than 0.01 µg/m³ in areas distant from traffic. Even with the relatively lower rural air content of lead, it is estimated that natural lead content of air in prehistoric times was even lower, well below 0.01 µg/m³. Natural lead content of air comes from volcanic eruptions, soil dust, and sea spray.

APPENDIX 4:
LEAD IN HUMAN BLOOD

Blood lead levels for persons in the U.S. and Europe revealed in numerous studies during the 1980s and early 1990s generally range from 7.1 to 14 micrograms per deciliter, while values now are under 4 µg/dl. In some areas of East and Southeast Asia, blood lead levels for women were measured at 1.9-6.5 µg/dl. Dietary lead was thought to contribute from 15% to 54% of the blood lead, while the rest was due to atmospheric contamination (i.e., dust) and smoking. A study of urban dwellers in China and Japan indicated that blood lead levels in the Chinese averaged 4.6 µg/dl with a dietary intake of just 25 µg/day, while in Japan, which has a cleaner environment, blood lead levels averaged 3.2 µg/dl with a dietary intake of 15 µg/day.

According to several recent studies, the blood levels of Taiwanese who were not in lead-related occupations ranged from 7.5-9 µg/dl, with only 10% of the tested population exceeding 14-15 µg/dl (the highest test value was 58 µg/dl). Higher blood lead levels were associated with being male, smoking, milk consumption, contamina-ted drinking water, and use of Chinese herbs. The role of herb consumption in blood lead levels varied among the studies; in one study it was thought to be the largest contributor (after occupational exposure, however) but in another study it was reported to be an unrelated factor.