2003

A Review of the endocrine disrupting properties of the organochlorine pesticides, and a critique and comparison of the laws and regulations governing their usage in the united states and the European union.

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A Review of the Endocrine Disrupting Properties of the Organochlorine Pesticides, and a Critique and Comparison of the Laws and Regulations Governing Their Usage in the United States and the European Union.

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Graduate Thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Environmental, Health & Safety Management

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April 2003

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This is dedicated to

Anita Shek

For without whom none of
this would have happened.
By giving me the idea,
The excuse,
And the motivation.

Thanks

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Chapter 1 Introduction

The purpose of this paper is to provide an introduction to the effects of organochlorine based pesticides on the immune system so as to better understand the importance of governmental restrictions put on their usage. The major laws and regulations the United States and the European Union will be compared, contrasted and critiqued for effectiveness toward limiting the damaging potential effects.

1.0 Pesticides

Each living creature on this planet has pesticides (includes herbicides, rodenticides, fungicides, biocides, and all the other sub-groups: unless noted otherwise) in their bodies. For the most part, these residues have been relatively harmless, just something that is in most plants as part of their makeup and as such pose no threat to us. Most people do not realize that plants expend energy in deterring pests, and therefore have evolved many ways of addressing this. After all, a nutshell is not there just to look pretty. However, some are more dramatic than others. It is estimated that the average person consumes 1.5 grams of plant-produced pesticides per day on average (http://socrates.berkeley.edu/mutagen//ames.PNASII.html), most coming

from coffee. Each plant has the capacity to defend itself from predation and are really only dangerous to the target species of pests.

The industrial revolution changed all of that. In an effort to supply more food to the growing masses, mankind worked to develop compounds that would keep pests off food crops. For the most part they were inert but a few were highly toxic, not only to the target species, but also to anything that came in contact with the compound. So while spraying tea and tobacco juice is fine, applying lead and mercury are not. Quickly these compounds found their way into the ecosystem where they proceeded to affect the lifecycles of all living things.

However, unlike the natural pesticides and the manmade ones like the tobacco spray, mercury and the like began to build up in the tissues of the plants and animals that were part of the web of life. As we move up the food chain we have discovered that compounds like mercury, and later, many of the modern pesticides, tend to bioaccumulate. That is, as the predator at the top eats lower life forms, it accumulates a very substantial level of the toxic compound in its tissues. Fortunately the signs of acute lead or mercury poisoning in humans has long been recognized and as such many governments prohibited the use of the more dangerous chemicals of the day from being applied to crops (WHO,UN).

Agricultural scientists worked towards creating new pesticides, ones that were safer for the farmers, yet still effective in ridding plants of pests.

In 1873 a scientist put a new compound together called Dichloro Diphenynl Thricloroethane (DDT), however, it would take 66 years, until 1939 that a Swiss scientist discovered that it was very effective at killing insects, for which he won a Nobel Prize(http://www.chem.ox.ac.uk/mom/ddt/ddt.html). At the time the scientific community as a great advancement against malaria and other insect borne diseases lauded it. History now shows that this was one of the bigger blunders of the scientific world, we are still dealing with the long-term effects of it, and even though it was banned in this country in 1973, it is still used to this day elsewhere. (www.greenpeace.org).

DDT is only one in a very large family of pesticides known as the organochlorines. All of them are loosely based on the same formula and operate with the same efficiency that DDT did. DDT interfered with generations of animals by interfering with their ability to reproduce; the best known is the Bald Eagle. They were once found in large numbers in every state except Hawaii, but by the end of the 1960's were all but wiped out here in the lower forty-eight states. The cause, it was discovered, was two fold. First, the mated pairs that laid eggs often accidentally crushed the eggs due to the thinness of the shells. The second was that even when they managed to raise a chick to adulthood,

often the bird was deformed and was either unable to mate, or showed no interest in mating. (Colborn, Dumanoski, Myers, 14).

This was also true of most of the larger populations of Herring gulls in the US, as well as the alligator and other swamp birds. In the North Sea, the Harbor Seal and several dolphin species were also dying by the score and having problems reproducing. This die-off reached a peak in the late 1980's when hundreds of thousands of dead seals in the North Sea were washing up on shores. At the same time, in the Mediterranean Sea, tens of thousands of dead dolphins were washing ashore. Experts agree that for every animal that washed ashore ten were probably lost at sea. (Colborn, Dumanoski, Myers, 160).

The seal dilemma was finally solved in 1992 when it was discovered that what killed the seals and dolphins was a form of canine distemper. But why did a disease that strikes only canines have such a disastrous effect on these two marine mammals? It is not like they are related. Scientists began to look at the chemical makeup of the North Sea (160).

It was possible that the pesticides could have had an effect on the seal's immune system, somehow forcing it to change in a way that would leave them open to infection from a disease that would otherwise not bother them at all. The years of living and feeding in the sea had altered their immune system with each

generation to such an extent that it left them open to something that should have otherwise been ignored (Colborn, Dumanoski, Myers, 159-163).

There are also examples of diseases striking humans that should not pose a threat, much like canine distemper should not have been a threat to the seals. HIV is one such a case. Since the HIV virus was finally isolated it has become one of the most studied of the major viruses that plague humanity. It was also discovered in the early 1990's that the HIV virus is latent in us all, but our immune system is more than strong enough to handle it and so poses no threat. (http://www.thebody.com/bp/feb01/word.html) While HIV tends to infect the nutritionally challenged (http://www.thebody.com/index.shtml), other chronic problems are becoming epidemic in our society. These diseases infect a cross section of the population, infecting people in all areas of society, regardless of race, sex, sexuality or socio-economic standing. Some of these chronic conditions include (www.cdc.gov)(Buranatrevedh, Deodutta)(Snedeker)(Menegon, Board; et al):

- Chronic Fatigue Syndrome (CFS)
- Multiple Chemical Sensitivity (MCS)
- Growth Disorders
- Attention Deficit Disorder (ADD)
- Hormonal Cancers

- Breast Cancer
- Parkinson's Disease

But even with careful balancing of the diet, adding supplements and doing everything you could to be healthy, your immune system would still be inferior to our ancestors of just 5 generations ago. It is important to understand what has so altered our immune systems in so short of a time.

I postulate that the use of pesticides may be the culprit of such effects. To support this contention, a review of their mechanisms of action are as follows:

1.1 Hormones

To say that the human body is complex is not even beginning to come close. Each second of each day the trillions of cells in us are performing multiple trillions of activities. And they do this with efficiency and time worn casualness. It is remarkable that life of any kind exists, considering, especially, ones as complex as the higher mammals.

Hormones are the actors that keep all cells in communication. A family of chemicals and amino acids that control every single activity that there is in all life forms. They control when we go through puberty and when we loose our hair; they are the secret of eternal youth, and the reason we age. They are also what builds a human (Levine and Suzuki).

Hormones control the mating and reproduction cycle. The process starts with the meeting of the prospective couple. The reason that people are initially attracted to someone is because of a family of airborne hormones called pheromones. These let the male know when a female is in estrus (heat) and starts the whole process. If the male is lucky, mating will occur, which requires a completely different set of hormones. Then if mating is successful, yet another set gets involved, and so on and so on, etc.

From the initial meeting to birth nine months later, thousands of different chemical reactions have to take place in the females' body to produce a child that is an amalgamation of the two parents genetics (Levine and Suzuki). For most of its development both the mother's liver and the placenta protect the fetus. However, the most important part of a pregnancy is the first week, usually before the female even knows she is pregnant, there the hormones of the endocrine system lay down the groundwork for the upcoming baby.

Unfortunately, it is also at this point that the zygote is at the greatest risk. More often than not, the zygote has problems and another set of hormones trigger a period that flushes the small multi cell zygote out of the body, thus terminating the pregnancy (Levine and Suzuki).

Hormones work like chemical keys that are constantly traveling through the body looking for the right door to open. In fact, this analogy is the one that is most often taught. Each hormone has a specific door it is looking for, these doors are called receptors, and each receptor has a specific function, from triggering electrical nerve impulses, to telling a fetus that it will have brown eyes and will be bald at the age of fifty. Genetics contribute to your whole life framework, and hormones are there to find the appropriate receptors at the appropriate time. And we tend to spend a great deal of time, energy and money trying to trick these receptors into not triggering (Schettler, Solomon, Valenti, Huddle, 4).

The body also has systems in place to make sure that these receptors are not triggered accidentally. There are many mechanisms built into us to make sure that all of the major life changing events happen when they are supposed to. Sometimes they fail, resulting in a multitude of different disabilities.

Hormones are key too much of life and the maturation process. Pesticides may mimic hormones in the body. They can also fit into the key lock of the

receptor, but can trigger a wrong response, or prevent a response. This problem has been discovered in the last fifty years (151).

Chapter 2 Background

2.0 Background of Food Production

All living creatures need to eat, it is one of the strongest primal urges that exist. Most species spend the vast majority of their waking lives in the search for food. Human kind is no different. Each species also tries to make their feeding time more productive and therefore less time consuming. Many different styles have been evolved, from larger mouths able to take in more feeding area (baleen whales), working in groups (wolves, lions) to even letting others do the work for you (remoras, lampreys). Even plants are not immune and will grow higher, or have deeper roots to gain the advantage. Some even produce herbicidal compounds that prevent other species from encroaching (black walnut tree) (http://www.extension.umn.edu/projects/yardandgarden/ygbriefs/h407blkwal-tox.html). Even early humankind formed larger groups to be able to feed better. The early hunter gatherer tribes were quite successful in feeding their people, the women and children would go out and gather edible plants, and the men would go hunting.

However, this style of life would only support a small group, and as we reproduced, strains were put upon the food gathering abilities of the group. Out of this agriculture was born. With the ability to grow food and domesticate

animals, people could, and had to, settle in a single place to produce food. This gave rise to larger and larger groups. This produced two distinct outcomes; one was the building of civilizations, and the other was to genetically isolate groups of humans from each other. This isolation allowed for genetic mutations to take hold, creating distinctly different groups of people.

But as time progressed, the ability to produce enough food was slowly falling behind our ability to reproduce. Famines became common, as well as wars over rich food producing areas. The Romans proceeded to take over larger and larger areas for the sole purpose of growing wheat to feed their ever-expanding population.

Much can be said about all of the common plants that we consider food. Mankind has hybridized plants for thousands of years working toward a goal of more food per acre planted. The upside of this is that yields per acre were increasing each year until recently. The last 20 years have shown a steady decrease in yields per acre, mainly due to soil depletion and pests. A pest or weed is simply some organism that is in the wrong place at the right time and therefore is interfering with the production of food. Controlling these pests is a major focus of the life of a farmer, and one to which a large part the day is devoted.

For thousands of years the main way of controlling these pests was through human labor. Eventually people started to use chemical warfare on the pests, mainly insects, by crushing up other plants and spraying them on the crops. This proved to be rather successful and stayed unchanged for many hundreds of years. Insects do not become immune to the plant essences; thus this type of pesticide does not allow the insects to mutate and become resistant to the plant based pesticide. Another benefit was that the farmer could easily grow the needed plants right on the farm, so there was no real cost to their usage (http://www.ams.usda.gov/nop/NOP/standards.html).

The problem that would arise periodically would be a disease that would wipe out a certain plant and plunge areas into famine. There are historically many examples of these blights. The Irish potato famine is an example. This was caused by the simple fact that the Irish had based their diet almost exclusively on potatoes, so that a disease could, and did, easily move through the country wiping out the food crops. Another, but lesser known blight was the one that wiped out all of the grape vines in France in the late 1800's. The cure for that was grafting American rootstock to the French grapes. Even today there is still the disease in the soil of France, and so you will not find a single vine that does not have a root grown in America (Vineopolis, London, UK).

Population exploded during the Industrial Revolution due to the ability to suddenly make more and more goods for the populace. Populations, especially in the cities, exploded as more jobs and money became available to the masses. These people needed to be fed and suddenly the old ways of farming were no longer providing enough food for everyone, and something had to be done (Ehrlich, Paul and Anne).

In the US, there was westward expansion, creating larger farms and ranches. However this was not so easily done in other areas of the world, especially Europe, where the land has been settled for along time and is scarce. So instead energy was put into creating stronger toxic compounds to keep pests of all types under control. Many of the compounds were highly effective, unfortunately they also had a tendency to poison the plants too, or make the food toxic to humans (Greenpeace).

Keeping the soil fertile was also a problem, until this time cow manure was the main soil fertilizer used, however, the need soon outstripped the supply and science looked towards producing fertilizers from other sources.

The single crop system that was prevalent and we can see why there were extensive food shortages at the end of the 19th century. Fortunately for Europe, the US had an almost limitless supply of fresh soil on which to grow food, and so

we became Europe's breadbasket. However, this started to become a problem in the early part of last century. With the single minded farming practices of the times, soils became barren and dry resulting in low, or in some cases, no yields. The great dust bowl of the 1920's is a good example. Farmers in the Midwest had, in a short period of time, depleted the soil to such a degree that after a period of drought, it dried up and literally blew away (Historychannel.com).

Eventually the drought and the depression ended and farming began again in earnest. Farmers had a new idea, crop rotation. This helped the soil remain fertile, making for stronger plants and in turn this helped to keep pests down. However, there was still not enough food being produced.

World War II provided the world with many great advances in science. One of which would be termed the 'Green Revolution' by historians. The main advance was the ability to synthetically produce pesticides, herbicides, fungicides and fertilizers as an offshoot of the petroleum chemical industry. This gave the farmer the ability to apply a chemical and all of the target species would die, and then apply other chemicals and the plants would be fertilized thus increasing yields exponentially. The 1950's were the largest increase in food production mankind has ever known. It seemed that we could raise an almost inexhaustible supply of food on existent agricultural land (Merchant),

Almost immediately all of the old farming practices like crop rotation or using certain plants as natural fertilizers were discarded. Integrated pest management was also discarded, to be replaced instead with vast stretches of the country planted with nothing but wheat and corn (the corn being used as cattle feed). And if an insect or disease hit a farm, the farmer would simply apply the proper chemicals and the insects were gone, and the disease cured. It seemed a truly glorious time for the farmers of the world.

These same compounds were also used to kill pests that did not harm crops, but were a threat to people. Vast stretches of jungles were sprayed with DDT to kill mosquitoes and tsetse flies, thus lowering the levels of malaria and other human diseases (http://www.cdc.gov/ncidod/eid/vol3no3/roberts.htm).

In the late 50's and early 60's a few people also noticed that there seemed to be less and less wildlife in areas where spraying was taking place. Some, including Rachel Carson, became alarmed and tried to do something to bring this problem to the attention of the masses. Carson wrote a book called 'Silent Spring' (1962) which brought home this problem. And even though this book is one of the most important written about environmental problems, she still only really dealt with issues related to wildlife when there was another, very insidious problem that these compounds were causing, one that would actually cause her death just 2 years after publication of her book. Unknown at the time was the

effect that these chemicals had on the human species. In her case it caused breast cancer that was diagnosed too late (Carson).

Because of Rachel Carson's book, and others, the 1960's were a time of awakening environmentalism. Suddenly the term 'Ecology' was everywhere and people started to take an interest in the chemical world around them. People started to notice that their world was not as clean as they thought, and many species were beginning to disappear. Incidents like the Cuyahoga River in Ohio catching fire, or the lack of Bald Eagles in the lower forty-eight states spurred people to start examining probable causes.

As we know now, it was DDT that almost caused the extinction of the eagles, yet it was not until 1973 that it was banned from use in the US. US companies still produce most of the worlds supply. However, we then import the goods DDT is used on (Mott, Snyder)(Colborn, Dumanoski, Myers, 139).

Back in the late 60's and early 70's, DDT was still widely used, along with many members of the same family, the organochlorines, to keep pests under control. However, farmers were noting that it took more and more sprayings at higher doses to keep the pests under control. The pests seemed to be adapting to the compounds, something they never did with the old plant based compounds.

The government, and the makers of the chemicals encouraged farmers that they should keep on spraying. And when the costs became prohibitive, the government, with tax money, subsidized them so that they could afford to keep using the chemicals and thus increase yields, even though there was already too much food being produced. So each year the government would pay farmers to not plant crops on certain amounts of acreage and would also pay farmers to use the artificial fertilizers and pesticides to increase the per acre yields (USDA).

Yet, even with all of these chemicals, yields peaked in the early 80's and have been steadily declining, even though our usage of chemical fertilizers and pesticides has increased per acre. The soils are so depleted that there is nothing left for the plants to use for food, and all the artificial fertilizers in the world will not make up the difference. Another problem is that the pests we have today are, for the most part, immune to the sprays, so that the farmer has to apply more toxic pesticides more often to achieve the same results. Industry is responding by inventing even more deadly pesticides that are being developed, rushed through testing, and dumped into our eco-system. Yet we still are not getting the same yields as we were, and in many cases the yields are at or below the levels of pre- green revolution.

It is known that even 20 years after the banning of DDT in the US, 100% of the population of the US has DDT in their tissues, and 99.99% of all the people in

the world are carrying DDT with them (World Health Organization). There are many studies that put a direct link between the consumption of pesticides, herbicides, fungicides and artificial fertilizers with many different health problems. The best studied is cancer, and the many different forms that are brought on by these compounds. Also well studied because of the Vietnam conflict is the adverse affect of 2.4.d and 2.4.t (otherwise known as Agent Orange) on the human nervous system. Mainly because of the sheer amount of Vietnam Vets who have multiple disorders due to their exposure to this common herbicide (http://www.lewispublishing.com/orange.htm).

Chapter 3 Literature Review

3.0 Introduction

The endocrine system is one of the largest, most studied and least understood of all the systems in the human body. It was first studied in ancient Greece and China several thousand years ago, and Europeans started looking into it 300 years or so ago. But yet there is still so much that is not understood (Colborn, Dumanoski, Myers, 74).

It is not clear how the endocrine system reacts to outside influences. It is know that many of it's functions are and how they affect living things, but it is not known how they react to stimuli that comes from another source other than ourselves, and weather it would make a difference if the stimuli were natural or artificial.

3.1 Endocrine System

The endocrine system is the oldest 'system' in our bodies. Every living organism has one, from the simple virus, to mankind. Each organism creates hormones to do specific tasks within it, and as such there are countless types of individual hormones, but the most common and important is estrogen. Estrogen is found in all life. It is found everywhere, from a bacterium during

reproduction, to plants and to humans. Not only that, but they are chemically identical (Colborn, Dumanoski, Myers, 74).

The endocrine system is one that extends throughout the entire body of the organism, and for this paper, humans will be the animals of interest unless stated otherwise. There are several organs that are associated with the hormone system: the pituitary glad, the thyroid, the adrenals and the sex organs, the ovaries and the testes (Colborn, Dumanoski, Myers, 32-33).

The pituitary gland is a gland at the base of the brain that is the control center for the endocrine system. From it are secreted different compounds that influence and control the other systems of the body, as well as the rest of the hormone system. For example, one of the main hormones that it controls is the growth hormone. In addition, the pituitary gland controls the thyroid, which is located in the front of the neck. The main job of the thyroid is to secrete thyroxin. Thyroxin is a hormone that regulates general metabolism. The adrenals, also governed by the pituitary, are located just above the kidneys. They produce adrenaline, but also produce cortisone and hydrocortisone. Lastly are the ovaries and testis, which produce estrogen, progesterone and testosterone (Colborn, Dumanoski, Myers, 32-33).

Hormones work very simply. When a specific need is identified by the pituitary gland, the gland sends hormone binding globulin (HBG) to whichever gland produces the hormone needed. This HBG then picks up the hormone and transports it to the cell in question where it releases it into the cell. The hormone then enters the cell to find a hormone receptor, and as a key fits into a lock, it joins the receptor, releasing an enzyme that enters the nucleus and tells the cell to do a function. All of this it does tens of thousands of times a minute for the entire lifetime of the organism, and the entire process may take only a few seconds to a few minutes. Without this process we would cease to function, we could not think, or control temperature, much less reproduce or grow (Schettler, Solomon, Valenti, Huddle, 151).

Pharmaceutical companies synthesize many hormones in labs that are routinely taken daily. Women for years have been taking artificial forms of estrogen when entering menopause to help ease the effects of that dramatic change of life, and the family of drugs that include Prozac are nothing more than lab produced forms of melatonin and seratonin. Even the natural supplement world has its own forms of bottled hormones, from natural melatonin and bovine growth hormone to soy isoflavones. Both of these industries are working with compounds to try to replace what our bodies may or may not be synthesizing on it's own (Balch and Balch).

However, as learned recently, sometimes there are long-term side effects that are unwanted and can be life threatening. It was discovered, the hard way, that steroids can inflict long-term damage to the brain, and many popular athletes have died due to several cancers that were directly traced back to their steroid use. Prescription estrogens are controversial due to the health problems associated with them. But the biggest backlash to date has been the widespread use of the drug DES (Diethylstilbestrol) that was routinely given to pregnant women from 1950 till it was pulled from the market in 1971. This artificial hormone was thought to be able to prevent miscarriages and other problems normally associated with pregnancy. However in the late 1960's and early 1970's it was discovered that not only did it not prevent any of the problems it was supposedly fixing, but instead was causing birth defects on an unheard of scale. However they were very subtle birth defects; not the ones that thalidomide caused where children were born with hands but no arms, instead DDS caused problems in the hormone system. The book, 'Generations at Risk' lists some of the discovered effects of a mother taking DES while pregnant:

"Later studies demonstrated that DES daughters often have abnormalities of their reproductive organs, reduced fertility, and unfavorable pregnancy outcomes, including ectopic pregnancies, miscarriages, and premature birth, as well as immune system disorders. DES sons are more likely to have small and undescended testicles, abnormal semen and hypopadias. DES mothers have a breast cancer risk about 35% greater than those not exposed." (Page 153)

DES daughters also tend to pass on some of the defects to their own daughters even though they themselves did not use the drug. At least three generations at this point that have been affected.

3.2 Pesticides

Since the beginning of agriculture humankind has been trying to control any perceived pests that may decrease the productivity of a field. The attempts were not spectacular until the advent of the 'green revolution' in the 1930's and 1940's. In pre and post WW II period science made great advances in the use and creation of chemicals. Just as antibiotics were seen as the great wonder drugs of the time, so were pesticides seen as the great defeater of the 'pest'. The first that was introduced was DDT. It was, and is, extensively used worldwide. The EU and US banned the use of it in 1973, and a short time later banned another member of its family, Lindane. These are included in the largest family of pesticides, the organochlorines. Others include: endosulfan, methoxychlor, heptachlor, toxaphene, dieldrin and others, all still available and on the market. All share the element chlorine somewhere in its makeup (Cadbury).

Below is a listing of popular pesticides that have been used in the last fifty years that have either endocrine disrupting properties, or are estrogen-like:

Table 3.2.1

TABLE 1

Some Endocrine-Disrupting and Estrogen-like Pesticides

	Endocrine-Disrupting Pesticides	Estrogen-like Pesticides
Herbicides	2,4,5-T	Atrazine
	2,4-D	
	Alachlor	
	Amitrole	
	Atrazine	
	Metribuzin	
	Nitrofen	
	Trifluralin	
Insecticides	δ-Hexachlorocyclohexane (δ-HCH)	δ-HCH
	Carbaryl	Kepone (chlordecone)
	Chlordane	1-Hydroxychlordene
	Dicofol	Dicofol
	Dieldrin	Dieldrin
	DDT and its metabolites	p,p′-DDT
	Endosulfan	o,p′-DDT
	Heptachlor and it epoxide	o,p′-DDE
	Lindane	p,p′-DDE
	Methomyl	DDT
	Methoxychlor	DDE
	Mirex	Endosulfan
	Oxychlordane	Heptachlor
	Parathion	Methoxychlor
	Synthetic pyrethroid	Toxaphene
	Toxaphene	

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They act on their intended targets in many different ways, from poisoning the target, through disruption of reproduction, killing eggs and larvae or stalling the development or change from one part of the life cycle to another (Mott, Snyder).

They are also developed to be persistent. What is the use of a compound that easily washes away? Newer pesticides are now being designed to quickly break down in the environment into inert simple compounds, but many of the older ones like Dichloro Diphenynl Thricloroethane (DDT) and many of the soil sterilizers, were made to last years without any loss of potency. In recent years its been discovered that many of the 'inert' forms were sometimes more deadly than the original chemical. Such a one is DDT; it breaks down into several different sub chemicals, Dichloro Diphenynl Ethylene (DDE) and Dichloro Chlorophenyl Ethane (DDD) being the more widely studied. It was found that while DDT is relatively safe to more complex animals, DDE was not. It was DDE that was responsible for most of the wildlife problems that resulted (http://pmep.cce.cornell.edu/profiles/extoxnet/carbaryl-dicrotophos/ddt-ext.html).

Pesticides have the ability to bioaccumulate in the higher predators to startlingly large amounts, sometimes in the parts per thousand (Colborn, Dumanoski, Myers, 103-104). Many of the pesticides work by disrupting the hormone systems of the target pest, changing the targets ability to reproduce by causing infertility, or reversing the sexes of the target. Many would attack the eggs and render them unviable for hatching.

As stated earlier, 99.99% of the world's population has DDT residue in their tissues, and 100% of Americans and Europeans cells contain DDT residue. The effects of such accumulation must be understood. Further, it is important to know if any other environmental chemicals may also mimic hormones in living systems (World Health Organization).

3.3 Other Natural and Synthetic Hormone Mimics

Science has discovered other common chemicals in our daily environment that mimic hormones in the body. Many are manmade, but some are found naturally occurring in our foods. The most famous of the manmade chemicals are the families of Polychlorinated Biphenyls (PCB's) and Dioxins.

PCB's

PCB's were first discovered in the late 19th century, but it was not until the 1930's that a practical use could be found for them. PCB's are simple to make; just mix biphenyl with chlorine. And because of this, there are now 209 members of the PCB family. Their first use was industrial, because they were in oil, but one that was non-conductive and non-flammable. They were used by the growing electrical industry to fill transformers. To date there are still hundreds

of thousands of PCB filled transformers worldwide. Soon they were also being used as a general lubricant for areas that required a safe alternative to petroleum lubes. Since they were considered safe, their disposal was often no more difficult than pouring out onto the parking lot, or mixing with waste oil to keep dust under control. In 1977 the EPA banned the production, transportation, sales or disposal of PCB's, but by that time over 1.2 million metric tons had been produced, and it is estimated that over 80% still exist in the environment in some form. Lab studies have concluded that PCB's contribute to the formation of certain cancers and other disorders. (http://www.epa.gov/opptintr/pcb/)

Dioxin

Another large family of chemicals is the Dioxins. There are 75 different members of the chlorinated dioxin family and 135 chlorinated dibenzofurans, a very close relative. Dioxins are a pollutant that is created mainly by burning things, and bleaching paper pulp. Dioxins have always been with us, but in very minute amounts, however, with the advent of the plastics age, the amount being created has jumped exponentially. Dioxin is also the deadliest man made chemical yet, it is known to be carcinogenic in the part per trillions (http://www.epa.gov/pbt/dioxins.htm). Dioxin is also under investigation for its ability to mimic hormones (http://www.epa.gov/pbt/dioxins.htm).

Plastics

Plastics are another group of suspected hormonal mimics. More specifically, the chemicals that are used to give plastics some of their properties, from ones that make plastic hard and rigid (nonylphenol), to ones that make it pliable and supple (bisphenol A). These are just two of the chemicals that are under study, and they are in everything, from our milk jugs to the safety linings in cans, and there is considerable evidence that they are able to leach from the plastics into the food stuffs that they hold (Schettler, Solomon, Valenti, Huddle, 180-182, 227).

Plants

Many plants produce estrogen as a defense against insects and animals that eat them. They flood the target with estrogen and estrogen like compounds to disrupt its ability to reproduce, and while in insects this might be easily tolerated, it is less tolerated when there is a disruption to livestock.

In the 1940's, sheep ranchers in Perth, Australia were alarmed to see that their normally healthy sheep were getting sick, and not reproducing. After several years of studies it was ascertained that the imported type of clover from

the Mediterranean region was the culprit, since it formed a powerful estrogen mimic in its leaves to protect it from pests. It was quickly dubbed 'clover disease' and took everyone by surprise (Colborn, Dumanoski, Myers, 75-78).

Plant estrogens are also found in our own food sources. At this moment, in health food stores around the world people are buying many foods made out of soy, a bean native to Japan that is easy to grow. It is high in protein and nutrients, and has a natural estrogen mimic called isoflavone. And since isoflavone is weak, being less than 3% as strong as estrogen, it is heartily recommended and sold in pill form for its reputed ability to protect people breast cancer as well as other forms of cancers. There is another chemical in soy that is actually 30% to 50% stronger than estrogen. This group is the coumestans. Soy, however, is not the only popular food that this group can be found in. It is also in beans, peas, spinach, sunflower seeds, alfalfa and clover. There are other foods that contain mimics, such as yams, which can contain diosgenin, which is converted to progesterone in the lab, and others (Cadbury, 88).

3.4 Summary

Hormone replacers and mimics are all around us, they are in the food we eat and the air we breathe, the water we drink. But by far the least understood

are the pesticides, and with dozens of new ones hitting the market each year. While there are controls of usage and release in place, they may not be practical. Each year the EPA and the FDA are petitioned by the chemical companies to let them sell their new pesticides, but neither agency has the manpower to test each and every one, so many times they use the companies own tests as their basis to release. They will often allow the sale of a chemical that is a very close relative of one already on the market, without any proper testing (EPA).

Chapter 4 Methodology

4.0 Methodology

The methodology for this research was a review of present and past articles and books that pertain to the topic. I also reviewed all of the pertinent laws and regulations of the US and the EU that pertain to this topic, since they are two of the four largest food producing regions. Also included was the citable past work related research.

4.1 Description of Methodology

In order to build this study, I will review the literature sources listed in the bibliography including:

- Books
- Articles, both online and in hand
- Web sites of relevant use
- Past college classes
- Text books

The target of the work will be to compare the knowledge of the effects of pesticides with the major provisions of EU and US laws and regulations governing their use.

4.2 Regulations

There are many regulations that cover the use of pesticides here in the US and the EU, I will be reviewing them for similarities and differences, out of this will come such information as:

- Similarities between the two entities
- Differences between the two entities
- Methods of policing the laws and regulations
- Applicable penalties and their application

With this information I plan to compare them to determine if there is one entity that is dealing with the issue of pesticide use better than the other. I intend to decipher whether the major tenets of EU and US regulatory law address the known exposure issues.

4.3 Objectives

The objectives of this research was to:

- Identify the main components of the Endocrine system
- Identify the Hormone mimicking of certain pesticides
- Identify the potential damage they are doing to the Endocrine system
- Review the pertaining laws and regulations
- Determine the adequacy of such laws and regulations
- Compare and contrast the handling laws and regulations of the US and EU
- Determine which governmental body has the stronger stance on usage of pesticides

Chapter 5: Laws and Regulations

5.0 Overview

Pesticides are powerful compounds that are designed to kill or neutralize a target species or a wide range of species'. When used properly they are very useful to the modern farmer in the control of pests and enable them to increase the yields per acre. Pesticides are also very valuable in the control of disease carrying species', such as mosquitoes and rats. When misused, or accidentally spilled into the environment in large amounts, they can become a powerful pollutant.

To help to prevent the misuse of pesticides, governments around the globe have come up with laws and regulations to control and regulate the use and manufacture of pesticides. Most countries have based the design of their laws of the model set by the United States (US) through the programs sponsored by the United Nations (UN).

This model is based on a law or set of laws that contain very specific regulations covering all aspects of the use and application of pesticides. This model includes allowable limits of exposure for both humans and the local environment. A large part of the model is the criminal side, what is considered

improper use and what are the penalties, from fines to imprisonment, for the misuse of the approved pesticides. The only major food-producing region that does not follow this model is the European Union (EU); their approach is based on programs and incentives instead of regulations and fines.

To further highlight the differences between the two different approaches I am going to compare two of the four major food producing regions, and look at the way they handle the use of pesticides. One will be the US, the model for most of the regulations world wide in respect to pesticide handling and usage; the other will be the EU. These two entities are also the largest consumers of pesticides, as the table below shows:

Table 5.0.1

Product group	Market share in percent						
	U.S.	Western Europe	Eastern Europe	Latin America	Asia	Others	World Total
Herbicides	34	30	6	8	15	7	100
Insecticides	18	20	8	9		14	100
Fungicides	9	48	5	6	28	31	100
Total share by region	**20**	**33**	**6**	**8**	**25**	**8**	**100**

Regional Market Share of Pesticides, 1991. Wossink and Feitshans

5.1 Laws and Regulations of the US

Federal regulation of the use of pesticides in the US is covered by a number of pieces of legislation and controlled by many different departments of the US government. The most important controlling body is the Environmental Protection Agency (EPA) through their control of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This is the main legislation that was created to control the use and manufacture of pesticides. There are other departments that have varying degrees of impact on the use of pesticides depending on the mandate set down to them by the Congress. They include:

- Food and Drug Administration- FDA
- Occupational Safety and Health Administration- OSHA
- United States Department of Agriculture- USDA
- Department Of Transportation- DOT

Each of these departments has a limited control over the use of pesticides due to the areas of their control, such as:

- FDA and their control of residue amounts in food (Federal Food, Drug and Cosmetic Act- FFDCA)(Food Quality Protection Act- FQPA) Public Law 104-170

- OSHA and worker safety through the Occupational Safety and Health Act and it's regulation, Hazard Communication Standards (HCS) 29CFR 1910.1200.
- USDA with the 1990 Farm Bill that includes the Federal Recordkeeping Requirement, requiring all records of use of Restricted Use Pesticides (RUPs).
- DOT with the Hazardous Materials Transportation Act, and the Commercial Motor Vehicle Safety Act. These two acts control the transportation of pesticides across the US.

The department with the greatest control over the use and marketing/manufacturing of pesticides is the EPA. The main legislation that they are able to use to control them is FIFRA. There are, however, many other pieces of legislation under their control that also pertain in some way to the regulation of pesticides. They are:

- **Clean Water Act (CWA) 33 U.S.C. 1251** This act protects water bodies and wetlands from undue pollution. It targets point (can be traced to a specific source such as a dump, or a spill of some kind) and non-point (cannot be traced to a specific source, but instead is considered run-off, leaching and application drift) source pollution. This act also encourages Best Management Practices (BMP), and works with the

individual States to establish Total Daily Maximum Levels (TDLs). The CWA also has a special provision that designates the Chesapeake Bay as a special area.

- **Clean Air Act (CAA) 42 U.S.C. § 7401** The CAA sets air quality standards for all pollutants, including air borne pesticides.
- **Safe Drinking Water Act (SDWA) 40 U.S.C. § 007f-300j-10** The SDWA prevents contamination of surface and ground water sources of drinking water, thus preventing the disposal of pesticides by injecting into any groundwater source. It also establishes Maximum Contaminant Limits (MCLs).
- **Resource Conservation and Recovery Act (RCRA) 42 U.S.C. § 6901** RCRA controls the treatment, storage and disposal of hazardous and municipal solid waste. RCRA also has in it the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA/Superfund). This act controls the clean up of uncontrolled releases of hazardous substances and does impact the businesses producing, storing or using "extremely hazardous substances" (EPA emphasis). It does not apply to any pesticide application that is not already covered by FIFRA, or handling and storage by farmers.

- **Endangered Species Act (ESA) 16 USCA § 1531** The ESA protects endangered and threatened species from the dangers of pesticides, besides other threats.
- **Toxic Substance Control Act (TSCA) 15 U.S.C § 2601** The TSCA regulates new commercial chemicals and existing (pre-1976) chemicals. This act can be used to support pesticide use restrictions where groundwater contamination is a risk.
- **Emergency Planning and Community Right-to-Know Act (EPCRA) 42 U.S.C. § 11001-11050** This act makes it mandatory for businesses to let their surrounding communities know what types of hazardous compounds they are using. Farmers and others that are under the jurisdiction of FIFRA are exempt.
- **Coastal Zone Management Act (CZMA) 16 U.S.C. § 1451** The CZMA controls sources of non-point pollution that impact coastal water quality. The use of this act is given over to the states to implement and to design pertinent programs.
- **Food Quality Protection Act (FQPA) 104 P.L. 170** (EPA shares authority of this with the FDA) this is actually an amendment to the FFDCA, but since it is also about pollution also falls under the jurisdiction of the EPA.
- **FIFRA 80 P.L. 104** Federal Insecticide, Fungicide, and Rodenticide Act.

FIFRA 80 P.L. 104

By far the most important legislation for the control of pesticides is FIFRA, the Federal Insecticide, Fungicide, and Rodenticide Act. It is also the oldest. FIFRA was first introduced to Congress as the Federal Insecticide Act in 1910 in response to USDA concerns about the 'sale of fraudulent or substandard pesticide products' (USDA). Specifically the act sets standards for the manufacture of Paris green, lead arsenate, insecticides and fungicides, and also provided for inspections, seizure of adulterated or misbranded products, and the prosecutions of violators (USDA).

The act remained unchanged until after World War II and the advent of the widespread use of synthetic pesticides across the US. In 1947, it was updated and renamed the Federal Insecticide, Fungicide, and Rodenticide Act. It has been amended several times since then to update the act as science moves forward. In 1970, the EPA was created and was given authority over FIFRA. In 1972 a new law entitled the Federal Environmental Pesticide Control Act (FEPCA) was passed that required that all new pesticides be registered with the EPA and classified as general or restricted use. This new law also changed the emphasis of pesticide regulation from quality assurance and adequate labeling of pesticide products, to the protection of public health and the environment from their potential hazards (EPA).

FIFRA has been amended several times since the 1960's; the last amendment was in 1996. This single piece of legislation covers all pesticides sold, distributed or used in the US that is not registered with the EPA. One important factor is that EPA registered does not mean EPA approved. Registration categorizes the toxicity of the pesticide and assures that the statements on the label reflect this. The act also stipulates that it is a violation of federal law to use a pesticide not in accordance with its label. (EPA)

FIFRA has several sections to it, besides dealing with registration; it also has sections on labeling, worker protection standards (WPS), certification and training and food safety. Each of these has specific areas of importance:

Labeling- Controls when and under what conditions pesticides are:

- Applied
- Mixed
- Stored
- Loaded or used
- When fields can be reentered
- When crops can be harvested
- Disposal of pesticides and their containers.

Worker Protection Standard (WPS) 29 USCS § 1854- Protects occupational safety and health of agricultural workers and pesticide handlers.

- Also sets agricultural use requirements on the label that cover farm, ranch, forest and greenhouse use of pesticides and what the Restricted Use Intervals (REI)(usually 12, 24 or 48 hours) are for each pesticide. This section of the label also contains information on how to comply with the manual concerning training in the use of the specific pesticide, oral or written warnings for misuse, central notification, recordkeeping needs and the use of Personal Protection Equipment (PPE).

Certification and Training (WPS) This section covers the training needs for users of:

- Restricted Use Pesticides (RUPs), these are pesticides that are deemed hazardous even when used according to the label requirements.
- Private applicators- use or supervise the use of RUPs to produce agricultural commodities on property owned or rented by themselves or their employers.
- Commercial applicators- use or supervise the use of RUPs on any property or any purpose other than that listed for private applicators.

- Applicators must be trained to use RUPs- they have to meet certain competency standards that each state sets the requirements for.

Food Safety- This section the EPA shares with the FDA to make sure that the foods that we consume meet FDA standards of acceptable pesticide residue levels.

These are the laws that the US government uses to control the usage, manufacturing, marketing and disposal of pesticides in the US. These laws give a framework and set guidelines for how pesticides should be regulated, but they very often leave implantation of the specifics to the states themselves.

5.1a Implementation

While the federal government, through the EPA and other departments, sets national policy, it is the states that often take the laws and conform them to the specific needs of the particular state. The states have the right to take any law that the federal government sets and rework it, as long as the states version of the law is not more lenient than the federal version. An example would be the DWI laws, the Federal government might set the limit at 0.1, and a state could then set their own limits at 0.08, but could not make them higher that the Federal limits, so a state could not make theirs 0.15. The same goes for local statutes on

exposure levels to any federally controlled compound (http://laws.lp.findlaw.com/getcase/US/501/597.html).

We have a three-tiered system in the US, the Federal government writes the regulations and then gives them to the states. The states can then accept the regulation as is, or make it more stringent before passing it on to the localities. The individual localities can also make a regulation tighter, but are not allowed to make it looser than the controlling body has already set, whether it is the state or the federal government. However, a state may decide to preempt the localities law if it wishes (http://laws.lp.findlaw.com/getcase/US/501/597.html).

The states are also responsible, for the most part, not only to implement the laws and regulations set forth from the EPA and others, but to also provide the facilities for inspections and the policing of the regulations. For a department like the EPA, that means that besides national offices, there are regional offices, and state offices, and each office will carry out differing activities and will have jurisdiction over different areas of the regulations. Often, there may be several different EPA offices involved, along with state and local authorities, all claiming to have jurisdiction over an issue.

5.2 Laws and Regulations of the EU

At a basic level, the European Union (EU) is set up very much like the US. At the top is the European Community government, below that are all of the member states, and below that are the different localities within the states themselves. Just like the US, the EU will pass a piece of legislation, then will send it to it's member states who may adapt it to their own needs. And like the US, no state can make a law more lenient than the original version form the governing body. The same line of reasoning stands for localities inside a member state.

But the members can choose not to pass EU Legislation. In the US the states are semi-autonomous but rely on the Federal Government for much of their funding and guidance. The US states have never been totally separated from the main overall governing body and as such have no real full government. The US is a very homogeneous country that shares the same set of ideals.

In contrast the EU is composed of states that until a very short time ago were completely autonomous countries, with completely differing cultures and priorities. And as such any controlling legislation has to take into consideration all of these differences, and as such they tend to be a bit more 'open-ended' than what is in the US.

The main piece of legislation that sets the standards of policy for the EU is a document entitled "Towards Sustainability: A European Community Programme of Policy and Action in Relation to the Environment and Sustainable Development", it is also known as the Fifth Environmental Action Plan (FEAP). This is a policy plan that lays the ground rules for all of the member states to implement their environmental laws. Part one of FEAP is titled "A policy and strategy for the environment and sustainable development within the European Community" and targets the areas of:

- Industry
- Energy
- Transport
- Agriculture
- Tourism

Each of these sections is given an overview of the main problems and the desires of the new policy to implement changes and corrections. This part then goes on to delve into the individual problem areas with more intensive policy making initiative.

Each section is then broken down into areas of concern, followed by a table with the headings:

- Objectives
- Targets up to 200
- Actions
- Time-frame
- Actors

This is the table for the agriculture section.

Table 5.2.1

Tabel 4: Agriculture and forestry

Objectives	Targets up to 200	Actions	Time-frame	Actors
Maintenance of the basic natural processes indispensable for a sustainable agricultural sectornotably by conservation of water, soil, and genetic resources	Standstill or reduction of nitrate levels in groundwaters.	Strict application of the nitrates directive	1994 ⇒	*MS* + AGR
	Reduced incidence of surface waters with a nitrate content exceeding 50 mg/l or giving rise to eutrophication of lakes and seas.	Setting of regional emission standards for new lifestock units (NH_3) and silos (silage)	ongoing	*MS* + LAs
		Reduction programme for phosphate use	1995	*EC* + MS
	Stabilisation or increase of organic material levels in the soil	Allocation of premiums and other compensating payments to be subject to full compliance with environmental legislation	1995 ⇒	*EC* + MS + LAs + AGR
Decrease in the input of chemicals to the point that none of these processes be affected	Significant reduction of pesticide use per unit of land under production and conversion of farmers to methods of integrated pest control, at least in all areas of importance for nature conservation	— Registration of sales and use of pesticides	ongoing	EC + *MS* + AGR
		— Control on sale and use of pesticides	1995	EC + *MS* + AGR
Equilibrium between input of nutrients and the absorption capacity of soils and plants		— Promotion of 'Integrated Control' (in particular training activities) and promotion of bioagriculture	1992 ⇒	EC + *MS* + AGR
Rural environment management permitting the maintenance of biodiversity and natural habitats and minimising natural risks (e.g. erosion, avalanches) and fires	15 % of agricultural area under management contracts	Programmes for agriculture/environment zones with premiums co-financed by FEOGA	1992 ⇒	*MS* + EC
		Protection of all endangered domestic animal races	ongoing	*MS*
	Management plans for all rural areas in danger	Re-evaluation of license conditions for irrigation and of state aids for drainage schemes	1995	*MS* + EC
		Training of farmers, promotion of exchange visits between regions with comparable environment management situations	1992 ⇒	EC + *MS* + LAs
Optimisation of forest area as to fulfill all their functions	Increase of forest plantation, including on agricultural land;	New afforestation and regeneration of existing forest, favouring the most adequate means for the environment (slow growing trees, mixed afforestation);	ongoing	EC + *MS* + LAs + *forest-owners*
	Improved protection (health and forest-fires)	Further action against forest-fires	idem	idem

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At the end of this section there is a table that compares the highlights of all five-target sectors for a quick comparison.

Table 5.2.2

Table 6: Programme framework for selected target sectors

Industry	Energy	Transport	Agriculture	Tourism	
Integrated pollution control — operating licenses — emission inventory — env. audits — env charges — Clean and low waste technology	Reduction in pollution — specific targets for CO_2, SO_2, NO_x — econ and fiscal incentives — safe disposal of nuclear waste	Cleaner cars and fuels — emission limit values — economic and fiscal incentives — vehicle testing — reduction of evaporation	Ecologically sustainable farming — extensification — reduction of chemical inputs — organic farming — consumer information — econ and fiscal incentives	Sustainable tourism, land-use, infrastructure — drinking water — bathing water — waste management — sustainable mobility	Sectoral impacts
Reduced waste/better waste management — inventory of wastes — econ and fiscal incentives — deposit/return system — high standards for disposal — civil liability	Development of renewable sources — R & D and promotion of — biomass, wind, wave, solar, hydro, geothermal	Rationalization of infrastructure — network planning — inter-modal choice — bottlenecks — communications	Forest development — systematic planting — fire protection — sustainable harvesting	Protection of coastal zones and natural manmade or built amenities — desertification — cultural heritage — forest fires — nature trails	Resources
Ecologically-friendly products — eco-label — product standards — consumer information — tax differentials	Reduction in energy consumption — econ. and fiscal incentives — cons. info and educ. — SAVE, THERMIE, JOULE — regulatory instruments — volunt. agreements	Improved driver behaviour — info and eduction — econ and fiscal incentives — choice of modes — traffic management	Rural development — land management control — rural tourism — inland fishing	Broader consumer choice — broader choice of options — better information — better seasonal spread of tourism	Behaviour

NB.: The instruments indicated above are not exclusive to the sectors in which they appear; they have been inserted in the sectors in respect of which they have the most obvious potential.

Reprinted from the Official Journal of the European Community, Page No C 138/41

Part II of FEAP is entitled "The Communities role in the wider international arena." This area outlines global issues that the EU is making policy on for their member states with an eye to the fact that what they do affects

a wider community than their own. Some of the categories covered in this 12-page section include:

- Environmental threats and issues
- Global issues
- International Cooperation
- Global Partnership
- Developing Countries
- Central and Eastern Europe
- UNCED: The United Nations' Conference on Environmental Development

Part III is entitled Priorities, costs, review. This section is three pages that cover exactly what the title indicates. It covers the:

- Selection of Priorities
- The question of costs
- Review of the Programme

The FEAP lists three actions for meeting these targets (1) registration of sales and use of pesticides, (2) control on sale and use of pesticides, and (3)

promotion of 'integrated pest control' and promotion of organic agriculture. (Oppenheimer, Wolf and Donelly) Many of the member states already have in place programs to establish quantitative timetabled usage reduction targets, with the passage of FEAP; it establishes an EU wide programme of equality.

There is another piece of legislation that controls the use, distribution, manufacture and introduction of new pesticides in the EU. It is Directive 91/414/EEC: The Plant Protection Products Directive. This covers all aspects of pesticide use, in the directive termed 'plant protection products'.
This directive brings together a multitude of other directives that cover many different aspects of the life cycle of a pesticide under one piece of legislation. Some of the directives it brings together include:

- Directive 67/548/EEC- Hazardous chemical listing
- Directive 80/1107/EEC- This protects workers from exposure to harmful chemicals
- Directives 82/501/EEC and 90/394/EEC- these specifically protect agricultural workers from exposure
- Directive 78/631/EEC- This is the chemical regulations of 1193 covering hazard listing information and packaging protocols
- Directive 79/117/EEC- this bans the placing on the market of certain substances in pesticides

- Reg. (EEC) no. 2455/92- exporting to the 3d world
- Reg. (EEC) no. 2092/91- organic standards of labeling
- Directives 74/63/EEC, 76/895/EEC, 86/392/EEC and 90/642- these all cover treated crops
- Directive 86/363/EEC- this covers treated animals
- Directive 80/68/EEC- covers ground water purity
- Directive 75/440/EEC- covers surface water purity
- Directive 80/778/EEC- covers drinking water purity

All of the above have an impact on the life cycle of pesticides; with the passing of Directive 91/414/EEC previous directives fall under the authority of a single directive. This also makes it easier for the manufacturer to invent, test and market a new product. As the Pesticides Safety Directorate (PSD), an Executive Agency of the United Kingdom's Department for Environment, Food and Rural Affairs web page states (http://www.pesticides.gov.uk/index-ns.htm):

The main elements of the Directive are as follows:

It is intended to harmonize the overall arrangements for authorization of plant protection products within the European Union. This is achieved by harmonizing the process for considering the safety of active substances at a European Community level and, although individual product authorization will remain the responsibility of individual Member States, establishing harmonized criteria for considering the safety of those products;

The Directive provides for the establishment of a positive list (Annex I to the Directive) of active substances which have been shown to be without unacceptable risk to people or the environment;

Annex I of the Directive will be built up over a period of time as existing active substances are reviewed (under a collaborative EC Review Programme) and new ones authorized;

Member States will only be able to authorize the marketing and use of plant protection products whose active substances are listed in Annex I, except where transitional arrangements apply (http://www.pesticides.gov.uk/ec_process/EC_overview_general/91414background.htm).

To get a new active substance included to the Annex I list, a company must submit certain data:

- Identify an active substance or the plant protection
- Describe their physical and chemical properties
- Their effects on target pests, and
- Allow for a risk assessment to be made of any possible effects on workers, consumers, the environment and non-target plants and animals.

This directive brings together all of the pieces of other directives that had impact on pesticide manufacture and use and forms one Directive that can be used as a guide. It also obliges the member states to prohibit the placing on the market and use of any pesticides in their territory that has not been authorized in accordance to the Directive's provisions.

5.2a Implementation

Unlike the US, that has the EPA at a federal level to over see the implementation of environmental laws and regulations, the EU has no such body. Instead they have at a EU level, a committee that oversees environmental issues concerning all of the member states. It is actually the responsibility of each member state to police, regulate and implement the policies and programmes passed down from the EU government. This makes any environmental problems a much more internal one. But if an issue crosses borders, then the original country may petition for help.

To use a variation of the example from before, if a spill happens in Germany, into a river that flows through Holland, it is the duty of Germany to inform Holland of an impending problem, but it is up to Germany to clean up the spill before it crosses the border. If it crosses, Holland will work on their side of the border, and Germany on theirs and will not cross unless asked to do so by the other country. If the cause of the spill is criminal, then Germany, as the country of origin, will conduct an investigation on their side with no help from Holland, unless the seek help. At the same time, there is no overall unit from the EU that can come in and help with the cleanup and investigation.

5.3 Comparison

Both the US and the EU can be easily compared, while the EU is not technically a single 'country', it behaves similarly to the US. These two are also of a comparable size, the populations are similar, with the EU being slightly larger, and their Gross National Product (GNP) numbers are very close. The US for the year 2001 had a GNP of 9963 billion and the EU for the same year had 8603.43 billion (US dollars). However with the addition of 13 more states being allowed to join in the nest few years, they will surpass the US to become the largest economic force in the world.

The biggest difference between the two entities is that in the US, the states have a very limited autonomy, whereas in the EU, each state has a great deal of autonomy to do as it sees fit. As an example, in the EU, if a member state such as Germany wanted to send military force to another part of the globe, it could do so without much interference from the EU, however, if a single US state wanted to do the same, it would not be allowed to since it does not have the autonomy to make such decisions that would affect issues outside of it's borders.

The US regulations also tend to be fairly complete. With pesticides, FIFRA and the other acts have set limits of exposure to certain pesticides dependent on certain criteria. The US regulations also have a section on criminality. Each of the acts contains provisions of fines and/or incarceration periods for the criminal violation of the said acts.

This type of governing makes it easy for a homogeneous handling of laws and regulations throughout the US, a violation in one state is also a violation in another, with the same general ramifications of non-compliance in each state.

In the EU, because of the autonomy of each member state, laws and regulations that are passed down from the EC have to be written in a form that will allow each member state to adapt the regulation to fit each state's individual requirement. FEAP is written in such a way, the document works on implementing programs, instead of regulations. This way a member state can take the program, with the dictated end result, and find a way to meet the goals that is right for the state. The EC sets the policy and goals that have to be reached by each member state, but then leaves it to the state to get there on their own.

Economics (as well as US regulations) are also an issue that must be incorporated into any policy issues taken up by the EC. In the US, the country is

generally on the same economic footing, wages are generally level for a certain job throughout the country, there are some small regional variances due to localized costs of living, but for the most part a worker can expect a shallow range of salary for a same job. This is very different from the EU, where economic standing differs greatly. The EC has to contend with the fact that it contains some of the wealthiest countries in the world per capita (Germany, France, UK) and some of the poorer ones (Italy, Greece, Spain, Portugal). The cost of living also varies greatly in the EU. Sweden, for example, has one of the highest costs of living indexes in the world. And the EU contains two of the most expensive cities to live in, London and Paris, while at the other end also contains some of the least expensive countries to live in, Italy, Greece, Spain and Portugal, with correspondingly inexpensive cities. These factors weigh heavily in any governing process and any kind of policy that will result in an economic expenditure for the member country.

With the regulations concerning pesticide use, FEAP and Directive 91/414, many of the member countries have already met or surpassed many of the goals set in these two documents, but other of the member states still a ways from compliance. So the EC must take this into account whenever setting any policy or plan.

5.4 Critique

The EU and the US present two different approaches to the issue of controlling the life cycle of pesticides, the EU's programme approach, and the US's regulatory approach. Each is as viable as the other, and is designed to fit within the system that it has to work with; each also has its strong and weak points.

The strength of the US system is the regulations. They spell out the expectation and how to follow it. Within the regulations are the guidelines for all aspects of pesticide use or manufacture. The regulations lay down the framework for the industry in very certain terms, leaving very little doubt.

US enforcement is more uniform. This is due to the guidelines that are set down in the regulations, it is plain where the line is of compliance, an individual or business can easily tell when they are in violation of the regulation by the limits set forth in each regulation. A counsel in the EHS department of a company has a readily available guide to what the law is that the company has to work within.

Comparable systems are another positive aspect of the US style of regulation, since it is set up for use through out the entire US, there is very little

differences between doing business in Massachusetts and California. This makes it much easier for a company or individual to do business through out the entirety of the US without having the need for a large staff of EHS people working on compliance issues.

The major downside to this style of regulatory control is the lack of flexibility. There is very little space for a company to move within the confines of the regulations. This could hamper development of new pesticides that might be safer for the environment, but might not be allowed due to a lack of regulatory leeway.

Another significant problem is that with the US system of controls, it can be difficult and time consuming for a business to procure all of the proper permits for a product since it is conceivable that one product or compound may be under the control of several different governmental bodies.

For the EU, the main strength is the flexibility that FEAP and Directive 91/414 offer to the different member states. The EC sets the parameters and end goals of the programme and gives the member states the freedom to implement the programme according to the needs and differences of the states. The US system assumes that each state in the US is basically the same as every other state in all aspects, whereas the EU understands that there are vast differences

between the needs of one state to another, and so plans it's programmes to meet the requirements of each member.

Also a strength is the ease at which an individual or corporation can get permitted, whether to use a pesticide, or introduce a new one. Since each member state has authority over it's own region, a company can petition one governmental body for an addition. The governmental body then takes the request to the full EC for a vote to add it to the Annex I section of Directive 94/414/EEC (http://www.pesticides.gov.uk/ec_process/EC_overview_general/91414backgr ound.htm).

Conversely, the problems with the EU FEAP style of regulatory compliance arise from the flexibility built into the system. Since there is no set limits or criteria, each member state can have a differing set of limits of use, possibly making it difficult for an individual or a corporation to do business throughout the EU, a discharge violation in Sweden, could be within the legal limit in Spain.

Enforcement is another issue, since there is no set standards passed down by the EC concerning fines and/or incarceration; it is up to the member states to set these limits. This can lead to widely differing standards from member state

to member state, possibly leading up to frictions between member states that share borders. If, for example, Spain has a higher allowable limit for per hectare pesticides use than France, it is foreseeable that on the French side of the border the levels of pesticides in shared water (either above or below ground) could be in violation from the runoff washing off of the fields from the Spanish side. And with the governmental style and autonomy of the member states, France would have little that they could do to correct the problem except bring it to the EC as a protest.

Neither of these two systems is ideal, since each is tailored to meet the specific needs of the region under their control. Perhaps if the US was more flexible, and the EU was more regulated there might be one system for the control of pesticides that could work for both the US and the EU.

5.5 Recent Events

In 1999, the EU started work on drafting the Sixth Environmental Action Programme (http://europa.eu.int), it strives to update FEAP and provide stronger future leadership. The first draft was released in January 2003. If and when it is ratified, it will replace FEAP as the overriding programme for environmental planning.

In building this new Programme, the writers examined many different theories and ideologies that pertained to the way we think about the environment. One of the more prominent ideologies that was examined was the Precautionary Principle. The Principle first introduced in its modern form at the First International Conference on Protection of the North Sea, in 1984 (http://www.mindfully.org/Precaution/Precaution-In-Action-Handbook.htm#xii), and has been used widely since. The principle basically states that in every action that can affect the environment, governments and businesses should be taking precautionary action before scientific certainty of cause and effect, so that if a new chemical or process is given the green light, it should be reviewed for the possibility that it could cause environmental damage, and judged on that basis, instead of current scientific knowledge.

This differs from the current risk assessment style of decision-making that was prevalent from the 1970's on. There are flaws in this usage of risk assessment for the drafting of environmental regulations. The Handbook for the Precautionary Principle (http://www.mindfully.org/Precaution/Precaution-In-Action-Handbook.htm) lists the issues with risk assessment very well (for full text, see appendix 1):

- *Risk assessment assumes "assimilative capacity,"*

- *Risk assessment focuses on quantifying and analyzing problems rather than solving them.*
- *Risk assessments are susceptible to model uncertainty.*
- *Risk assessment allows dangerous activities to continue under the guise of "acceptable risk."*
- *Risk assessment is costly and time-consuming.*
- *Risk assessment is fundamentally undemocratic.*
- *Risk assessment puts responsibility in the wrong place.*
- *Risk assessment poses a false dichotomy between economic development and environmental protection.*

There are many tools that can be used to implementing and carrying out a precautionary principle; here again the Handbook states these very well:

- *Bans and phase-outs.*
- *Clean production and pollution prevention.*
- *Alternatives assessment.*
- *Health-based occupational exposure limits.*
- *Reverse onus chemical listing..*
- *Organic agriculture.*
- *Ecosystem management.*
- *Premarket or pre-activity testing requirements.* (http://www.mindfully.org/Precaution/Precaution-In-Action-Handbook.htm#iv)

What they have done is to provide a listing of parameters that a company or government may follow to provide a guide or framework to implementing better environmental laws and regulations. This guide also makes for a system wherein a company moving from one country to another, or doing business in multiple countries, will be more able to anticipate the environmental needs of the new location. And since this principle applies to all entities, it can be more useful than the current ISO's.

This way of thinking did not spring up overnight; the origins of this principle can be traced back hundreds, if not, thousands of years. The Amish concept of 'bearing witness' is a similar idea. Bearing witness is the ideology that, if you perceive a danger or threat you are bound by honor and God to intercede. It was this ideology that Greenpeace was formed around. (Greenpeace) A far older example comes from the Iroquois Confederation of 1142, and part of it states:

> "In our every deliberation, we must consider the impact of our decisions on the next seven generations" (http://www.ratical.org/many_worlds/6Nations/index.html)

One of the most important expressions of the precautionary principle internationally is the Rio Declaration from the 1992 United Nations Conference on Environment and Development (ibid). The sentiment can also be found in the

US's 1990 Pollution Prevention Act as part of the Untied States Code Title 42, the Public Health and Welfare Chapter 133. This act states:

> The Congress hereby declares it to be the national policy of the United States that pollution should be prevented or reduced at the source whenever feasible; pollution that cannot be prevented should be recycled in an environmentally safe manner, whenever feasible; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner. (http://www.epa.gov/opptintr/p2home/p2policy/act1990.htm)

While not fully following the principle, it contains parts of it. Other acts followed, but none have been fully implemented in the US.

In the EU, the principle has been widely accepted and heralded, several EU member states, Denmark, Sweden and Finland have adopted the principle as part of their official environmental policy. (http://europa.eu.int). In 1999 the European Environmental Bureau (EEB) issued this statement:

> On December 14, 1999 the European Environmental Bureau (EEB) released an official position on the precautionary principle. The position was published in contribution to the drafting of a Commission's communication on the Precautionary Principle.The EEB has strongly criticised the non-democratic process, which has been followed, by stating: "The Commission has not consulted or officially informed stakeholders about the content and the scope of this planned paper. This raises concern, that an intransparent and non-participatory process might end up in restrictions for using the principle." (http://www.ecoglobe.org.nz/precprin/prec3110.htm)

There are still concerns from environmental groups that the chemical industry will try to gut the effectiveness of the principle, it is heartening that the EEB is taking the principle seriously.

Chapter 6: Summary

Pesticides are here to stay; they have infiltrated every place on the globe and every living thing. They are found in the polar ice and the depths of the Amazon jungle (Greenpeace). Pesticides have had some very beneficial effects; their use in the fight against malaria and other insect borne disease has been very positive and well documented. Food production grew for many years after their introduction, however, discoveries in the last 40 years show that there is a price to pay, a sudden change in the overall environment of Earth. We know that in using pesticides people can face environmental and health risks on at least four fronts:

1. The direct users of pesticides such as manufacturers, home users, who are less likely to be properly trained in correct handling, and farmers.
2. Pesticide residue in the water, air and soil occurring from the water runoff of farms, evaporation from soil, drift from aerial spraying or similar sources.
3. Food products imported from countries not supporting the DDT ban.

4. The changing biodiversity of the planet caused by the use of pesticides. For humans, the past 50 years have shown decreased fertility rates, and increased the rates of cancer, chemical sensitivities, and hormone related birth defects (Colborn, et al). New diseases, AIDS, Ebola, CFS, MCS to name a few, have also emerged since the advent of synthetic pesticide use.

Governments work continuously towards optimal conditions of pesticide use and production. Laws and regulations set limits for exposure and toxicity, and specify labeling and proper handling procedures.

Yet they have forever changed our lives. These compounds are in every part of our lives and in every cell of our body. During the tenure of their use we have witnessed the decline of fertility and the rise of cancers and birth defects, as well as the introduction of new threats to our species. Science is just beginning to understand the changes that they have made to us.

Though differing in style, the EU and the US share a common goal concerning the use and manufacture of pesticides, which is to reduce the risk to the people living under the control of these two governing bodies, and improve the health and safety of the general environment. The United States uses laws and regulations set into being by Congress and controlled by various

government agencies. Agencies like the EPA and FDA, with the States and localities also providing assistance. The US has an arsenal of laws to provide the backbone to an overall environmental policy. The Clean Air Act, and its sister the Clean Water Act, FIFRA, RCRA and many others provide the guidelines that government and business have to work in to achieve environmental compliance.

The European Union has a different approach to controlling environmental pollutants. Since the EU is a grouping of autonomous countries working under a common governmental umbrella, the approach they take is of necessity different, and less binding. Each member state works with its own existing laws, or implements new ones that will bring them in compliance with goals set up by the European Commission.

While the approaches are different, the goals are the same, to safeguard the people under their rule against the ravages and hazards of pesticides and pollution in general. How this is done is still hotly debated. There are two main camps of thinking; one is to let the businesses themselves become more 'green' and thus making advances towards a cleaner environment. The other is to let the governments make regulations that will force compliance. The main tools for use are the ISO's, 9000, 14000 and 14001, and the precautionary principle. As in all things the answer is not black or white, but a shade of gray in-between. The ISO's offer business the chance to follow a long term plan through the use of a set

of instructions, that in the end will earn them a certification. The precautionary principle gives governments (and business) a set of guidelines that if followed will result in a stronger environmental regulatory base. Through a mixture of government regulations and corporate responsibility, and the combination of ISO certifications and the implementation of ideas like the precautionary principle, the US and EU, can have a positive direct impact on the environmental health of their populations.

Pesticides are a part of modern day life. The damage caused by their use has far ranging effects which need long term planning. Even under optimal conditions where an equal amount of food could be produced without the use of synthetic pesticides, the residuals already in existence will affect all living organisms for decades to come. (Colborn, et al) This is something we will have to live with for generations, only the future will be able to tell us how many generations there are going to be and what future health issues pesticides will inflict on us.

Appendix 1
Full text of Precautionary Principle points

Risk assessment assumes "assimilative capacity," that is, that humans and the environment can render a certain amount of pollution harmless. Eliminating risk altogether is not a plausible outcome of risk assessment. Risk assessment is used to manage and reduce risks, not prevent them. This deters more fundamental efforts to institute clean production.

Risk assessment focuses on quantifying and analyzing problems rather than solving them. It asks how much pollution is safe or acceptable; which problems are we willing to live with; how should limited resources be directed? While these are valid questions, they bar more positive approaches: how do we prevent harmful exposures; move toward safer and cleaner alternatives; involve society in identifying, ranking, and implementing solutions?

Risk assessments are susceptible to model uncertainty. Current risk assessment is based on at least 50 different assumptions about exposure, dose-response, and extrapolation from animals to humans. All of these have subjective and arbitrary elements. As a result, the quantitative results of risk assessments are highly variable.

Risk assessment allows dangerous activities to continue under the guise of "acceptable risk." Risk assessment provides an air of quantitative, technical sophistication to inexact, assumption-laden, and politically driven science. It allows the continuation of activities that lead to greater pollution and degradation of health under the premise that it is either safe or acceptable to those who are exposed. It staves off regulation and action in the face of uncertainty and insufficient evidence.

Risk assessment is costly and time-consuming. A single risk assessment may take up to five person-years to complete. It ties up limited resources in trying to quantify and rank risks when the effects of exposures may already be obvious (see dioxin analysis above). Risk assessments take resources away from prevention-focused solutions.

Risk assessment is fundamentally undemocratic. Those exposed to harm are rarely asked whether exposure is acceptable to them, what biologist Sandra Steingraber labels a violation of fundamental human rights, or toxic trespass. Risk assessment traditionally does not include public perceptions, priorities, or needs, and while some efforts have been made to involve the public in risk-assessment processes, widespread public participation in either scientific analysis or decision-making is not a likely prospect in the coming years. No mechanisms for this exist. The risk-assessment process is most often confined to agency and industry

scientists, consultants, and sometimes a high-tech environmental group. Public involvement in risk assessments has generally only legitimized a pernicious process.

Risk assessment puts responsibility in the wrong place. It assumes that society as a whole must deal with environmental harm, and assumes a scarcity of resources for this task. The contention that "society" does not have enough resources for all environmental protection activities diverts attention from those responsible for harm, those who created it, not those who have suffered from it. If scarcity is a factor, it would be wise to shift government resources from studying problems ad infinitum to identifying safer alternatives to potentially dangerous activities.

Risk assessment poses a false dichotomy between economic development and environmental protection. Regulatory agencies often attempt to tie the "scientific" process of risk assessment to cost-benefit analysis, linking science and economic policy in environmental decision-making. The agencies fail to consider, however, the question of who assumes the costs and who reaps the benefits. Moreover, the economic benefits of pollution prevention and toxics use reduction strategies have been clearly demonstrated. An important consideration is that the cost of under-regulating will typically be greater than over-regulating, when considering subsequent clean-up and health costs.

Bans and phase-outs. A ban or phase-out could be considered the strongest precautionary action. At least 80 countries ban the production or use of a small number of highly toxic substances. The Nordic countries have particularly advanced the use of bans as a public health strategy. These countries see bans and phase-outs as the only way to eliminate the risk of injury or disease from a very toxic chemical or hazardous activity. Several chemicals, including cadmium and mercury, are now being phased out in Sweden. The International Joint Commission (see later discussion) recommended a phase-out of industrial chlorine chemistry in the Great Lakes region.

Clean production and pollution prevention. Clean production involves changes to production systems or products that reduce pollution at the source (in the production process or product development stage). Other clean-production activities address the dangers of products themselves, introducing sustainable product design, bio-based technologies, and the consideration of raw material and energy consumed in product creation, as well as questioning the fundamental need for products.

Alternatives assessment. Alternatives assessment is an accepted methodology as well as an underlying component of precaution. For example, the U.S. National Environmental Policy Act calls on the federal

government to investigate alternatives (in an Environmental Impact Statement), including a no-action alternative, for all of its activities (or activities it funds) determined to have potential environmental impacts. Citizens have the right to appeal decisions if a full range of options is not considered. Several European countries have initiated such programs for all potential industrial polluters. Nicholas Ashford at the Massachusetts Institute of Technology has developed a structure for chemical accident prevention called Technology Options Assessment. Under this scheme, companies would be required to undertake comprehensive assessments of alternative primary prevention technologies and justify their decision if safer alternatives were not chosen.

Health-based occupational exposure limits. Over a period of several years, a group of occupational health experts in the United States has developed a list of occupational exposure limits based on the lowest exposure level at which health effects have been seen. These levels are proposed as new occupational exposure limits.

Reverse onus chemical listing. Proposals in Denmark and the U.S. have been put forward to drive the development of information on chemicals and their effects. In Denmark, one proposal would require a chemical to be considered the most toxic in its class if full information on its toxicity was not available. A U.S. proposal would require that. all chemicals produced in high volume, for which basic toxicity information did not exist, would be added to the toxics-release inventory for emissions and waste reporting.

Organic agriculture. The U.S. Department of Agriculture is considering using the precautionary principle as a rule for deciding whether new technologies and substances may be permitted in organic agriculture. Although these decisions are now based on risk assessment upon evidence of "measurable degradation," organic agriculture lends itself to the precautionary approach. It is risk averse, premised on the principle of avoiding substances and practices that might cause harm rather than waiting for proof of harm.

Ecosystem management. Biodiversity issues are suited to the precautionary principle because their complexity and geographic scope increase scientific uncertainty, and because the results of errors can be devastating. Risk assessment and other tools have been unable to predict and prevent such disasters as the devastation of marine ecosystems and the collapse of fisheries. Ecosystem management, like epidemiology, calls for new approaches to the philosophy of science and new standards for human intervention. Applying the precautionary principle would suggest, for example, that interventions must be reversible and flexible. Any mistakes must be correctible.

Premarket or pre-activity testing requirements. The Federal Food and Drug Act requires that all new pharmaceuticals be tested for safety and efficacy before entering the market. This model could be applied to industrial chemicals and other activities.

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