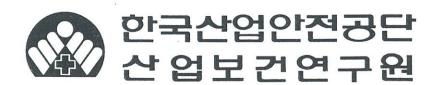
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Risk Assessment of New Industrial Chemical in Korea (1992-1996)

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Risk Assessment of New Industrial Chemical in Korea

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-Abstract-

From 1992 to 1996, 331 new industrial chemicals have been assessed by the Korean Industrial Safety Corporation (KISCO) funded by the Ministry of Labor (MOL) in Korea. The number of new industrial chemicals produced and the quantity of each of these chemicals increase annually. Sixty six percent of the new industrial chemicals submitted to the MOL had mutagenicity data and only 18 chemicals tested positive in mutagenicity tests. Seventy six percent of the new industrial chemicals had acute toxicity data and among them only 19 chemicals were classified as toxic chemicals by the Chemical Substance Examination Corps (CSEC) in the Ministry of Environment (MOE). The new industrial chemicals mainly used as raw materials for pesticides, dyes, paint and ink, motor oil, and PVC, plastic, and rubber. Most of the new industrial chemicals were imported from USA, Germany, Switzerland, and Japan. As a member country of the Organization for Economic Co-operation and Development (OECD) since 1997, Korea is now on the verge of lowering the trade barriers and complying with OECD directives vis-a-vis new chemical risk assessments.

신규화학물질의 유해성조사 보고서

이 준연, 유 일재 산업안전공단 산업보건연구원 산업독성연구실 인천시 부평구 구산동 34-6

I. 서론

우리나라에서는 7개 부처에서 13개의 화학물질관련 법규로 화학물질이 관리되고 있다 (1) (Table 1). 환경부의 유해물질관리법에 의해 478개의 유독물질이 규제되고 있고, 노동부의 산업안전보건법에 697의 유해화학물질이 관리되고 있으며, 농림부의 농약법 비료법 사료법에 의하여 248개의 농약, 비료, 동물사료가 규제되며, 보건복지부의 마약법, 향정신성의약품관리법에 의하여 100개의 마약과 향정신성 의약품이 규제되고 있으며. 식품침가제 86종도복지부의 식품위생법에 의해 규제되고 있다. 위험물질과 화약은 각각 내무부의 소방법과 총포화약무기류 단속법에 의해 규제되며, 고압가스는 통산부의 고압가스안전관리법, 방사선물질은 과기처의 원자에너지법에 규제되어지고 있다.

Table I. Acts related to the chemical substance management.

| Class | number of substance | Governing Ministry | Act |
|-------------------|---------------------|-----------------------|----------------------------|
| Toxic chemicals | 478 | Environment | Noxious Chemical Substance |
| | | | Control Act |
| Health hazard | 697 | Labor | Industrial Safety and |
| chemicals | | | Health Act |
| Pesticides, | 248 | Agriculture | Agrochemicals Control Act |
| fertilizers | | | Fertilizer Control Act |
| animal food | | | Animal Food Control Act |
| Pharmaceuticals | 100 | Health & | Pharmaceutical Act |
| Narcotics | | Welfare | Narcotics Act |
| Psychotropics | | | Psychotropic Drugs Control |
| | | | Act |
| Food additives | 86 | Health & | Food Sanitation Act |
| | | Welfare | |
| Dangerous substan | nces | | Fire Control Act |
| Gun powder | | | Gun, Knife, Gun power |
| | | | Control Act |
| High pressure gas | ses | Trade and | High Pressure Gas Safety |
| | | Industry | Management Act |
| Radioactive | isotopes | Science & | Nuclear Energy Act |
| substance | * | Technology | |

신규산업화학물질에 관한 유해성심사제도는 산업안전보건법 40조와 (2), 환경부의 유해 [일관리법 7조 (3). 산업안전보건법에서의 신규화학물질 심사의 목적은 직업병예방과 쾌적 한 작업환경의 제공이 목적이며, 유해화학물질관리법에서의 신규화학물질의 유해성심사는 국 한 건강증진과 유해화학물질심사와 관리를 통하여 환경을 보전하기 위하여서이다. 이 보고 한에서는 주로 산업안전공단 산업보건연구원이 노동부의 의뢰를 받아 5년간 수행한 산업화학 물질의 유해성심사에 대하여 중점적으로 논하고자 한다.

신규화학물질의 유해성 심사가 1992년에 시행된이래 산업안전공단은 노동부의 의뢰에 니해 사업주로부터 제출된 유해성심사보고서에 따라 근로자의 건강장해방지를 위해 필요한 시설, 설비의 설치 또는 정비, 보호구의 비치 등에 대한 조치등을 취할 수 있도록 심사하여 노동부에 보고하였다. 이 보고서에서는 1994년 부터 1996년 까지 행한 신규화학물질의 유해 성심사를 종합검토하고 장래의 신규화학물질 유해성 조사에 대해 전망하고자 하였다.

II. 결과

1992년부터 1996년까지 331개의 신규화학물질에 대한 유해성심사가 행해졌으며 물질수는 계속 증가하는 추세로 1997년에는 200여건의 신규화학물질의 유해성심사가 행해질 것이라고 예측된다 (Table II). 그리고 22개의 물질이 노동부 고시 96-15 신규화학물질의 유해성조사기준에 의한 정보보호를 요청하였다 (Table II).

Table II. Number of new industrial chemicals assessed and number of chemicals requested for the protection of information (from 1992 to Dec 31, 1996).

| Year | 1992 | 1993 | 1994 | 1995 | 1996 | Total |
|----------------------|------|------|------|------|------|-------|
| Assessed | 23 | 40 | 74 | 47 | 147 | 331 |
| Protection requested | | - | - | . 2 | 20 | 22 |

자세한 화학물질의 유해성 자료가 수록되어있는 1994년 부터 1996의 자료들을 분석하였다. 신규화학물질 종사근로자수는 1994년 880명, 95년 565명, 96년에 1218명으로 증가추세에 있으며, 그중 남성근로자가 대부분을 차지하고 있었다 (Table III). 신규화학물질의 양도 해마다 증가하여 94년 608.85 ton, 1995년 1465.2 ton, 1996년 2894.2 ton으로 계속 증가추세에 있다 (Table III).

Table III. Amount (in tons) of new industrial chemical reported and number of workers dealing with new industrial chemicals (from 1994 to Dec 31, 1996).

| 1994 | 1995 | 1996 | Total |
|------------|-----------------------|---|--|
| 608, 85 | 1,465.2 | 2, 894. 2 | 5, 058. 25 |
| 880 | 565 | 1,218 | 2,663 |
| 727 153 | 489 76 | 993 225 | 2, 209 454 |
| | 608, 85 880 727 | 608. 85 1, 465. 2 880 565 727 489 | 608.85 1,465.2 2,894.2 880 565 1,218 727 489 993 |

신규화학물질의 유해성심사 신고업체들은 제조업체 (135 업체)와 무역업체 (133 업체)로서 거의 같은 양상을 보여주었다 (Table IV). 268종 신규화학물질의 물리적성상은 138종이 고체분말상태였고, 액체상태가 127종, 기체상태가 3종이었다.(Table IV).

Table IV. Type of business involved with new industrial chemicals and physical properties of new industrial chemicals (from 1994 to Dec 31, 1996).

| | Type of busines | Phys | Physical prope | | |
|-------|-----------------|---------|----------------|--------|--------|
| Year | Manufacturing | Trading | Gas | Liquid | Powder |
| 1994 | 38 | 36 | 3 | 23 | 48 |
| 1995 | 21 | 26 | - | 27 | 20 |
| 1996 | 76 | 71 | - | 77 | 70 |
| Total | 135 | 133 | 3 | 127 | 138 |

268종중 145종 (66.4%)의 물질들은 변이원성시험자료가 있었고, 90종 (33.6%)는 변이d 원성시험자료가 없었다 (Table V). 7종의 화학물질이 에임즈시험 양성이었고, 11종의 화학물 질이 염색체이상시험 양성이었으며 소핵시험이 양성인 물질은 없었다 (Table V).

Table V. Mutagenicity data for new industrial chemicals (from 1994 to Dec 31, 1996).

| Year | Number of | Absence of | Presence of | F | Posit | ive |
|-----------|--------------|---------------|----------------|-------|-------|-----|
| | chemicals | data | data | Ames | CA | MN |
| 1994 | 74 | 14 | 60 | _ | 6 | - |
| 1995 | 47 | 20 | 27 | 1 | 1 | _ |
| 1996 | 147 | 56 | 91 | 6 | 4 | - |
| Γotal | 268 | 90 (33. | 6%) 145 (66. | 4%) 7 | 11 | |

Ames, Ames test; CA, chromosomal aberration; MN, micronucleus test.

204 종의 (76.1%) 종의 화학물질이 급성독성시험 (경구, 경피, 흡입) 자료를 제시하고 있었고, 64 (23.9%) 종의 화학물질은 급성독성시험자료가 없었다. 19종의 화학물질이 환경 부의 유해성심사에 의해 유독물질로 분류되어있었다 (Table VI).

Table VI. Toxicity data for new industrial chemicals (from 1994 to Dec 31, 1996).

| Year | Number | Absence | Presence | | | | Number |
|-------|-----------|---------|----------|--------|--------|---------|-------------|
| | of | of | of | oral | i.d. | inhl | of |
| | chemicals | data | data | LD50 | LD50 | LC50 | toxic chem. |
| | | | | | ~ | | |
| 1994 | 74 | 18 | 56 | 3/53 | 1/37 | 1/16 | 3 |
| 1995 | 47 | 4 | 43 | 1/43 | 0/15 | 2/12 | 2 |
| 1996 | 147 | 42 | 105 | 10/104 | 0/59 | 5/27 | 14 |
| Total | 268 | 64 | 204 | 14/200 | 1/111 | 8/55 | 19 |
| | | (23.9%) | (76.1%) | (7.0%) | (1.0%) | (14.5%) | (7.1%) |

[/] indicate chemicals with the data/number of chemicals.

174 (64.9%) 종의 화학물질에 대하여서는 작업환경에서의 근로자들에게 필요한 조치를 취하는데 필요한 피부독성이나 안구독성에 대한 자료를 제시하고 있었다 (Table VII).

Table VII. New chemicals with dermal toxicity and ocular toxicity data (from 1994 to Dec 31, 1996).

| Year | Number of | Absence of | Presence of | Po | sitive | 3 |
|-------|-----------|------------|----------------|-------------------------|-------------------|---------------|
| | chemicals | data | data | Skin Irrit. (sen) | Skin corrosive | Eye Irrit. |
| 1994 | 74 | 34 | 40 | 17 | 1 | 14 |
| 1995 | 47 | 11 | 36 | 14 | 1 | 14 |
| 1996 | 147 | 49 | 98 | 33 | 2 | 29 |
| Total | 268 | 94 (35, | .1%) 174 (64. | 9%) 54 | 4 | 57 |

Irrit., irritation; sen., sensitivity.

i.d., intradermal; inhl, inhalation.

신규산업화학물질의 용도는 23.9%가 농약의 원료, 15.3%가 염료제조, 11.2%가 페인트와 잉크의 제조원료, 10.8%가 자동차의 윤활유, 10.4%가 PVC, plasctic, 고무 제조의 원료 등으로 사용되었다 (Table VIII).

Table VIII. Uses of new industrial chemicals (from 1994 to Dec 31 1996).

| 1. Pesti 2. Dye 3. Paint 4. Motor | and Ink | 20 | 7 7 | 37 | 64 (23.9) |
|--|------------------|-----|--------|----|-----------|
| 3. Paint | | | 7 | | |
| | | 10 | 1 | 24 | 41 (15.3) |
| 4. Motor | | 10 | 5 | 15 | 30 (11.2) |
| | oil | 5 | 9 | 15 | 29 (10.8) |
| 5. PVC, | Plastic, Rubber | 5 | 3 | 20 | 28 (10.4) |
| 6. Antic | xidizer | 3 | 5 | 10 | 18 (6.7) |
| 7. UV St | abilizer | 5 | 2 | 7 | 14 (5.2) |
| 8. Leath | er treatment | 4 | 3 | 6 | 13 (4.9) |
| 9. Deter | gent | 4 | 3 | 2 | 10 (3.7) |
| 10. Other | 'S | | | | |
| Medi | ator in | | | | |
| phar | maceuticals | 4 | - | 1 | 5 (1.9) |
| Fire | extinguisher | 3 | | 1 | 4 (1.5) |
| Clea | ning solvent | 1 | 2 | - | 3 (1.1) |
| Adhe | sion accelerator | r - | - | 3 | 3 (1.1) |
| Cata | lyzer | - | = | 2 | 2 (0.7) |
| Hair | spray | - | 1 | - | 1 (0.4) |
| | ent reenforcing | - | - | 1 | 1 (0.4) |
| ager | | | | | |
| Fabr | ic softener | - | - | 1 | 1 (0.4) |
| Ligh | nt sensitizer | - | - | 1 | 1 (0.4) |

신규산업화학물질은 5.6%만이 국내에서 제조되었고, 나머지 94.4%는 외국에서 수입되었으며, 주요수입국은 미국 (33.6%), 독일 (18.3%), 일본 (17.5%), 스위스 (13.4%), 영국 (4.1%) 등의 순으로 수입되었다.

III. 고찰

1992년 산업안전보건법에 의한 신규화학물질유해성조사 실시된 이후 해마디 신규산업화학물질 수는 증가 하였으며, 증가추세에 있다. 한국의 1997년 부터 OECD회원국으로서 신규화학물질에 대한 유해성평가는 OECD의 수준으로 변화하게 될것이라도 생각된다. 물질의 사용량에 따라 14-28일의 반복투여독성자료나 피부와 안구자극시험자료를 요구하게 될 것이다. 국내에서 새로이 생산되는 신규화학물질의 독성자료도 우수실험실운영기준 (Good Laboratory Practice; GLP)을 갖춘 실험실에서 산출될 전망이다. OECD의 GLP에 관한 결정사항은 1997년국내법 (환경부의 유해화학물질관리법)에 반영되어 곧 1997년 7월 시행될 전망으로 있다. 한국정부와 관련기관 기업들은 OECD수준에 부합하는 독성연구실을 갖추기위하여 노력을 하고 있다.

한국의 화학산업은 급속히 팽창하는 산업으로, 1994년 정밀화학관련분야 총생산량이 145억 달라였으며, 그중에 의약품이 32%, 화장품이 20%, 페인트가 12%, 염료가 6%를 차지하고 있다. 그중, 12억달라의 화학물질이 수출되었으며, 44억달라의 화학물질이 수입되어 30억달라의 무역적자를 보이고 있다 (4). 그리고 국내에서 생산되는 화학물질의 양과 수는 해마다 중가하고 있는 추세이다.

노동부는 신규화학물질심사에서 오는 행정간소의 일환과 무역장벽을 낮추기 위한 노력으로 신규화학물질의 유해성 심사에 관한 관련법규를 개정하여, 신규화학물질에 관한 유해성심사를 일원화하여 유해성심사에 관하여서는 자료를 환경부에 제출하여 유해성심사를 받게하고, 노동부에는 환경부에 제출한 유해성심사자료결과와 MSDS를 자료를 첨부하여 제출하도록하였다. 이는 산업안전보건법의 목적인 작업환경에서 근로자의 건장장해를 예방하기 위한 조처를 취하고자 함이다.

신규화학물질의 심사를 위해 사업주가 제출한 자료를 살펴보면 특히 변이원성시험자료는 발암성의 예측자료로서 작업환경에서 장기적으로 유해물질의 폭로로 부터 발생하는 직업성암의 예방에 중요한 자료이고, 피부, 안자극성 자료는 근로자의 직접적인 물질폭로로부터보호할 보호구와 응급조치를 위해 필요한 자료임에도 불구하고, 수년간의 신규화학물질의유해성심사의 결과에서 보이는 바와 같이 많은 자료들은 변이원성시험의 자료와 피부, 안구자극성의 자료가 제출되지 않았다. 이는 어떤 화학물질들은 중합체 (Polymer)이기 때문에 불용성으로 변이원성시험자료를 산출할 수 없는 경우도 있지만 어떤 자료들은 직접실험한 자료가 아니라 유사물질의 자료에 의존하여 변이원성자료를 추정해낸 경우도 있었다. 이는 환경부의 유해화학물질관리법에 의한 유해성심사에는 유독물질의 분류를 위한 급성독성의 자료와환경독성의 자료가 근거가 되기때문에 이 분야의 독성자료를 등한시하지 않았나 생각된다. 그리고 앞으로는 사업주가 제출한 신규화학물질의 제조 사용 공정도의 신뢰도를 확보를 위한위한 실사가 행해져야 하리라고 생각되며, 앞으로 신규유해물질의 장기적 폭로에 의한 근로. 자의 직업성 암을 예방하기 위한 보완책이 수립되어져야 하리라고 본다.

IV. 참고문헌

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Risk Assessment of New Industrial Chemical in Korea

1996. 12.

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bstract

From 1992 to 1996, 331 new industrial chemicals have been assessed by the Korean industrial Safety Corporation (KISCO) funded by the Ministry of Labor (MOL) in Korea. The number of new industrial chemicals produced and the quantity of each of these shemicals increase annually. Sixty six percent of the new industrial chemicals submitted to the MOL had mutagenicity data and only 18 chemicals tested positive in nutagenicity tests. Seventy six percent of the new industrial chemicals had acute coxicity data and among them only 19 chemicals were classified as toxic chemicals by the Chemical Substance Examination Corps (CSEC) in the Ministry of Environment (MOE). The new industrial chemicals mainly used as raw materials for pesticides, dyes, paint and ink, motor oil, and PVC, plastic, and rubber. Most of the new industrial chemicals were imported from USA, Germany, Switzerland, and Japan. As a member country of the Organization for Economic Co-operation and Development (OECD) since 1997, Korea is now on the verge of lowering the trade barriers and complying with OECD directives 7is-a-vis new chemical risk assessments.

I. Introduction

In Korea, chemicals are controlled by 7 different ministries with 13 different chemical related acts as shown in Table I (1). Laws concerning new industrial chemical risk assessment are described in article 40 of the Industrial Safety and Health Act (ISHA, 1995) in the Ministry of Labor (MOL) (2) and in article 7 of the Noxious Chemical Substance Control Act (NCSCA, 1994) in the Ministry of Environment (MOE) (3). The purpose of ISHA is to prevent occupational diseases, and to provide comfortable working environments, while the purpose of the NCSCA is to promote the health of the public, and to preserve the environment through assessing and regulating the hazardousness of chemicals. We will mainly focus on the new industrial chemical risk assessment that is managed by ISHA in this paper.

Table I. Acts related to the chemical substance management.

| Class | number of | Governing | Act |
|------------------|-----------|-------------|----------------------------|
| | substance | Ministry | |
| | | | |
| Toxic chemicals | 478 | Environment | Noxious Chemical Substance |
| | | | Control Act |
| Health hazard | 697 | Labor | Industrial Safety and |
| chemicals | | | Health Act |
| Pesticides, | 248 | Agriculture | Agrochemicals Control Act |
| fertilizers | | | Fertilizer Control Act |
| animal food | | vi . | Animal Food Control Act |
| Pharmaceuticals | 100 | Health & | Pharmaceutical Act |
| Narcotics | × | Welfare | Narcotics Act |
| Psychotropics | | | Psychotropic Drugs Control |
| | | | Act |
| Food additives | 86 | Health & | Food Sanitation Act |
| | | Welfare | |
| Dangerous substa | ances | | Fire Control Act |
| Gun powder | | | Gun, Knife, Gun power |
| | | | Control Act |
| High pressure ga | ases | Trade and | High Pressure Gas Safety |
| | | Industry | Management Act |
| Radioactive | isotopes | Science & | Nuclear Energy Act |
| substance | | Technology | |
| | | | |

Article 40 (1) of ISHA states that "Any employer who desires to manufacture or import any chemical substance other than those as prescribed by the Presidential decree (hereinafter referred to as 'New Chemical Substances'), shall submit to the Minister of Labor the report on the result of examination on the harmfulness of such new chemical substance, under conditions as prescribed by the Presidential Decree, except in the following cases. Chemicals exempted by this Act are the new chemical of daily necessities of the general consumers, or of small quantity import, or of lower danger and injury" (2).

Since a double review process that previously existed has been changed, an employer nowadays can submit toxicity test results to the MOE, however not to the MOL, to manufacture or import as described in article 6 (1), and in (2) of the NCSCA (1994). "(1) Any person who desires to manufactures or import the chemical substance as prescribed by the Presidential Decree, shall report it to the Minister of Environment with materials necessary for examination on the noxiousness of such chemical substance, such as its nature, safety, etc." "(2) The chemical substance as referred to in Paragraph (1) shall not be manufactured or imported without undergoing the examination on noxiousness conducted by the Minister of Environment under Article After toxicity test results are reviewed by the Chemical Substance Examination 7". Corps (CSEC) in the MOE, the corps decides which classification chemicals will receive, such as "toxic chemical" or "specified toxic chemical" in order to regulate. An employer can submit results from the CSEC to the MOL. An employer can request the protection of chemical information to MOL thereby preventing the release of this information. The period of chemical information protection lasts 3 years initially, and can be extended an additional 3 years. The MOL, upon receiving a report on toxicity test (including CSEC results), can order the concerned employer to maintain or install facilities and equipment, and keep protective equipments (ISHA article 40 (4)).

Since new industrial chemical substance risk assessment has been initiated by ISHA in 1992, the Korean Industrial Safety Corporation (KISCO) supported by the MOL has been conducting the new chemical risk assessments to provide necessary measurements, to maintain or install facilities and equipment, and to keep protective equipment. In this paper, we describe the outcome of our 3 years of new industrial chemical risk assessments from 1994 to 1996 and the prospects of assessment in the future.

II. Results

A total of 285 chemicals have been assessed by KISCO from 1992 to 1996. The number of chemicals assessed have increased annually (Table II).

Table II. Number of new industrial chemicals assessed and number of chemicals requested for the protection of information (from 1992 to Dec 31, 1996).

| Year | 1992 | 1993 | 1994 | 1995 | 1996 | Total |
|----------------------|------|------|------|------|------|-------|
| Assessed | 23 | 40 | 74 | 47 | 147 | 331 |
| Protection requested | - | | - | 2 | 20 | 22 |

A total of 22 chemicals were requested and granted for the protection of chemical information. The detailed data on the new chemicals were only available to us from 1994 to 1996. There were 2663 workers dealing with new chemicals in total, and they were mostly male workers (Table III). The amount of new chemicals increased annually and reached 5,058.25 tons by 1996 (Table III).

Table III. Amount (in tons) of new industrial chemical reported and number of workers dealing with new industrial chemicals (from 1994 to Dec 31, 1996).

| Year | 1994 | 1995 | 1996 | Total |
|-------------------|------------|-----------|------------|---------------|
| Tons | 608.85 | 1,465.2 | 2,894.2 | 5,058.25 |
| Number of workers | 880 | 565 | 1,218 | 2, 663 |
| Male Female | 727 153 | 489 76 | 993 225 | 2, 209 454 |
| | | | | |

The types of businesses related to the new chemicals were manufacturing and trading or wholesale (Table IV). The physical properties of these 285 new chemicals

varied; 138 were in powder form, 127 were in liquid form, and 3 were in gas form (Table IV).

Table IV. Type of business involved with new industrial chemicals and physical properties of new industrial chemicals (from 1994 to Dec 31, 1996).

| | Type of busines | Physi | Physical property | | | |
|-------|-----------------|---------|-------------------|--------|--------|--|
| Year | Manufacturing | Trading | Gas | Liquid | Powder | |
| 1994 | 38 | 36 | 3 | 23 | 48 | |
| 1995 | 21 | 26 | _ | 27 | 20 | |
| 1996 | 76 | 71 | - | 77 | 70 | |
| Total | 135 | 133 | 3 | 127 | 138 | |

66.4% of the chemicals had mutagenesis data collected from running chromosomal aberration test, Ames test or similar level tests required by the NCSCA (Table V). The remaining 33.6% of chemicals did not have mutagenesis data, because these chemicals were polymers with high molecular weight. 7 chemicals had positive results in the Ames test and 11 chemicals had positive results in the chromosomal aberration test (Table V). There were no chemicals that had positive outcomes in the micronucleus test (Table V).

Table V. Mutagenicity data for new industrial chemicals (from 1994 to Dec 31, 1996).

| Year | Number of | Absence Presence | | Positive | | ive |
|-------|--------------|------------------|----------------|---------------|----|-----|
| | | of | of | | | |
| | chemicals | data | data | Ames | CA | MN |
| | - | | - | | | |
| 1994 | 74 | 14 | 60 | _ | 6 | - |
| 1995 | 47 | 20 | 27 | 1 | 1 | - |
| 1996 | 147 | 56 | 91 | 6 | 4 | _ |
| | | | | | | |
| Total | 268 | 90 (33 | .6%) 145 (66.4 | 1 %) 7 | 11 | - |

Ames, Ames test; CA, chromosomal aberration; MN, micronucleus test.

Since the Korean NCSCA requires the results of acute toxicity tests, mutagenesis tests in vitro or equivalent tests to be assessed by the CSEC in the MOE, we checked the presence and absence of acute toxicity data. 204 chemicals (76.1%) had acute toxicity data at either LD50 or LC50 (Table VI). 64 chemicals (23.9%) had no acute toxicity data. 19 chemicals (7.1%) had been assessed and classified by the CSEC of the MOE as toxic chemicals from 1994 to 1996 (Table VI).

Table VI. Toxicity data for new industrial chemicals (from 1994 to Dec 31, 1996).

| Year | Number of chemicals | Absence of data | Presence of data | oral LD50 | i.d. LD50 | inhl LC50 | Number of toxic chem. |
|-------|---------------------------|-----------------------|------------------------|------------------|--------------|--------------|-----------------------------|
| | | | | | | | |
| 1994 | 74 | 18 | 56 | 3/53 | 1/37 | 1/16 | 3 |
| 1995 | 47 | 4 | 43 | 1/43 | 0/15 | 2/12 | 2 |
| 1996 | 147 | 42 | 105 | 10/104 | 0/59 | 5/27 | 14 |
| Total | 268 | 64 (23.9%) | 204 (76.1%) | 14/200 (7.0%) | 1/111 (1.0%) | | 19 (7.1%) |

[/] indicate chemicals with the data/number of chemicals.

174 chemicals (64.9%) were furnished with skin or ocular toxicity data. This data is important because it provides proper measures to protect workers' health (Table VII).

i.d., intradermal; inhl, inhalation.

Table VII. New chemicals with dermal toxicity and ocular toxicity data (from 1994 to Dec 31, 1996).

| Year | Number | Absence | Presence | Po | sitive | |
|-------|-----------|---------|----------------|--------|-----------|--------|
| | of | of | of | | | |
| | chemicals | data | data | Skin | Skin | Eye |
| | | | | Irrit. | corrosive | Irrit. |
| | | | | (sen) | | |
| 1994 | 74 | 34 | 40 | 17 | 1 | 14 |
| 1995 | 47 | 11 | 36 | 14 | 1 | 14 |
| 1996 | 147 | 49 | 98 | 33 | 2 | 29 |
| Total | 268 | 94 (35 | 5.1%) 174 (64. | 9%) 54 | 4 | 57 |
| | | | | | | |

Irrit., irritation; sen., sensitivity.

23.9% of these chemicals were used for pesticides, 15.3% for dyes, 11.2% for paint and inks, and 10.4% were used as for raw materials for PVC, plastic and rubber (Table VIII).

Table VIII. Uses of new industrial chemicals (from 1994 to Dec 31 1996).

| Use | s | 1994 | 1995 | 1996 | Total (%) |
|-----|--------------------------|------|------|------|-----------|
| 1. | Pesticide | 20 | 7 | 37 | 64 (23.9) |
| 2. | Dye | 10 | 7 | 24 | 41 (15.3) |
| 3. | Paint and Ink | 10 | 5 | 15 | 30 (11.2) |
| 4. | Motor oil | 5 | 9 | 15 | 29 (10.8) |
| 5. | PVC, Plastic, Rubber | 5 | 3 | 20 | 28 (10.4) |
| 6. | Antioxidizer | 3 | 5 | 10 | 18 (6.7) |
| 7. | UV Stabilizer | 5 | 2 | 7 | 14 (5.2) |
| 8. | Leather treatment | 4 | 3 | 6 | 13 (4.9) |
| 9. | Detergent | 4 | 3 | 2 | 10 (3.7) |
| 10. | Others | | | | |
| | Mediator in | | | | |
| | pharmaceuticals | 4 | - , | 1 | 5 (1.9) |
| | Fire extinguisher | 3 | | 1 | 4 (1.5) |
| | Cleaning solvent | 1 | 2 | _ | 3 (1.1) |
| | Adhesion accelerato | r - | - | 3 | 3 (1.1) |
| | Catalyzer | - | - | 2 | 2 (0.7) |
| | Hair spray | - | 1 | _ | 1 (0.4) |
| | Cement reenforcing agent | - | - | 1 | 1 (0.4) |
| | Fabric softener | - | - | 1 | 1 (0.4) |
| | Light sensitizer | - | - | 1 | 1 (0.4 |
| | | | | | |

Although 5.6% of the new industrial chemicals were produced domestically, most of the new industrial chemicals were imported from foreign countries such as the USA (33.6%), Germany (18.3%), Japan (17.5%) and Switzerland (13.4%) (Table IX).

'able IX. Imported and domestic production of new industrial chemicals (from 1994 to Dec 31, 1996).

| | 1994 | 1995 | 1996 | Total (%) |
|-------------|------|------|------|-------------|
| omestic | | | | |
| production | 3 | 3 | 9 | 15 (5.6%) |
| imported | 71 | 44 | 138 | 253 (94.4%) |
| USA | 20 | 21 | 49 | 90 (33.6%) |
| Germany | 3 | 10 | 36 | 43 (18.3%) |
| Japan | 17 | 5 | 25 | 47 (17.5%) |
| Switzerland | 23 | 3 | 10 | 36 (13.4%) |
| UK | 4 | 3 | 4 | 11 (4.1%) |
| France | 1 | 1 | 4 | 6 (2.2%) |
| Spain | 1 | _ | 5 | 6 (2.2%) |
| Netherlands | 1 | _ | 2 | 3 (1.1%) |
| Italy | _ | - | 2 | 2 (0.7%) |
| Singapore | 1 | | _ | 1 (0.4%) |
| India | | - | 1 | 1 (0.4%) |

III. Discussion

Since 1992 when ISHA initiated new industrial chemical risk assessment, many chemicals that have filed for the risk assessment have increased annually and will increase in the future. The Korean Ministry of Environment, which is responsible for the risk assessment of new industrial chemicals, require mutagenicity and acute toxicity data for these new industrial chemicals. Korea will be a member country of the OECD (Organization for Economic Co-operation and Development) starting 1997. The risk assessment for new industrial chemicals will change to comply with OECD directives for chemical management (5), requiring additional repeated dose toxicity (14-28 days) and skin and eye irritation tests depending on the amount produced or imported. Toxicity data of domestically produced chemicals, some of which have been tested in foreign GLP (Good Laboratory Practice) laboratories, could be tested in domestic GLP laboratories in the near future. The OECD directive for GLP (9) has been accepted and will be finalized to a legislative measure in a 1996 session of the Korean National Assembly, and will be effective by 1997. Korean government and private sectors are now trying to improve existing toxicological laboratories to achieve the level required by the OECD GLP.

Korean chemical industries are growing faster. In 1994, 14.5 billion dollars of chemicals have been produced. Among them chemicals for pharmaceuticals, cosmetics, paint, and dyes were 32%, 20%, 12% and 6%, respectively in 1994. 1.2 and 4.4 billion dollars of chemicals have been exported, and imported, respectively, showing a 3.2 billion dollar trade deficit (4). Amount and number of new chemicals produced domestically are expected to increase year after year.

Korean government, a member country of the OECD and the WTO (World Trade Organization), is now trying to lower trade barriers. The double risk assessment procedure for new industrial chemicals that existed in both the MOL and MOE has been unified. An employer can submit the toxicity data to the MOE only. After being reviewing by the CSEC, an employer can submit the outcome of the CSEC's report to the MOL to provide measures for protecting the health of workers in the workplaces.

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