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ARIES: SYSTEM FOR HEALTH EFFECTS ASSESSMENT IN INDUSTRIAL RISK

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TOXIC MATERIALS
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COMPUTERIZED SIMULATION

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INTRODUCTION

Our work is being developed within the frame of the Post- Seveso Directive (82/501/EEC) about major accidents hazards of certain industrial activities. The objective of this Directive is to know the processes and the products stored in an industry in order to prevent accidents. It is important not just to know all about the industry but also to know the possibles consequences in case an accident happens. In this situation it is evident that the knowledge about the expected effects must be obtained as quick as possible in order to act to prevent further consequences.

Within the 82/501/EEC Directive there is a list of products considered toxic and dangerous that delimits the development of our work on the health effects produced by an exposure to toxic chemicals accidentally released. We faced this objective giving priority to the necessity to have a quick answer about the effects produced in case of an accident.

One of the most important problems to establish the health risk associated with a potential exposure to toxic chemicals is the lack of data that let realize a quantitative assessment. This is due to the absence, for most of the products, of a previous established dose-response relationship. If we specify more detailed the sort of exposure as in case of an accident, where is going to be an acute exposure, the absence of data is more evident. Nevertheless, in this frame of unknowledge about causal relation exposure-effect, there are few possibilities for numerical description that let quantify the risk to which population is yield.

Logically, the development of the different kinds of models to assess quantitatively the risk is the goal of many research programs developed in differents international and national Research Centres. However, as the research in this field of quantitative models needs time,

it is interesting replace the absence of these models, specially for accidental situations, with other problem-approach solutions.

Any reasonable approach to assess human health effects for chemicals starts with the search and analysis of the sort of data related with it. It is necessary point out that information acquisition, previous stage for assessment, pose serious problems itself, now that not only is disperse, but usually quantitative and qualitatively differs as a function of the specific chemical product.

If we analyze the existing information specifically for each chemical in order to use it in the assessment, we can find these situations:

- Products for which the existing information is minimal and does not let realize the effects assessment.

- Products for which the amount of data is such as big that the management and the selection of the aspects needed for the assessment, in an accidental release, is very complex.

- Situations between both above, where it can be a lot of information but not necessarily the one needed for the assessment. This is, from a quantitative point of view, the most frequent situation.

The selection of specific data cannot be limited to the one refered to an accidental exposure, and effects on human beings principally because of the absence or partial knowledge of this sort of data. This fact makes necessary to consider other sort of data as that from experimental animals, cell cultures, etc. Consequently is essential have into account more aspects that just those directly related with human toxicity, fact that makes more complex not only information acquisition but also data management. To succeed quickly in information acquisition step, it is necessary the identification of the best information sources that

guarantee on one side, its scientific quality and on the other side, that most of the existing information has been acquired. Among the possibles information sources is clear the priority given to selected data bases because some of them can offer not only the points related above but also permit manage the data dynamically.

The fact to consider a great variety of aspects, and that each product must be considered as a particular case, makes necessary design a specific methodology in order to manage the data for the assessment. This methodology has to be performanced by a tool with a dynamic and flexible structure that let work with great and varied amount of data.

In relation with the aspects named until now there are some points to develop for a qualitative assessment:

1.- Define which aspects related to biological effects produced by toxic products are necessaries to consider for a health effects assessment in case of an accident.

2.- Have the maximum data, related to the paragraph above, about those chemicals that point out the priorities of the project, as those within 82/501/EEC Directive.

3.- Design a system not only to store the selected information but also to apply the methodology designed in order to facilitate the quicker health effects assessment for those chemicals included in phase 2.

In relation with the first point we have already mentioned the necessity to cover the unknowledge about human toxicity with other sort of data as experimental results on animals, physico- chemical properties, data from workers, etc. These aspects are further detailed in "ARIES: Contents, structure and informatic support".

In relation with the third point we propose ARIES[1] as a tool to manage this information in order to assess the effects.

Shortly, ARIES could be defined as a methodology for health effects assessment based on one side, on the analysis of the existing information about chemicals toxicity and on the other side on the systematic treatment of specific parameters and exposure index about each chemical. Basically the principal aim of ARIES is cover the actual absence of quantitative models to achieve a first approach to the health effects assessment related to toxic chemicals exposure.

ARIES is designed to facilitate the health effects assessment produced by chemicals, and in such quick way that it could be used in case of accident as a first approach to know the consequences. The idea is focused on the development of a system that lead us to a quick answer about expected effects produced by the toxic chemical products. This system, once identified the product, compares the external concentration of the chemical released with a board of selected values with the aim to provide a first approach to the magnitude of the expected effects. Then, and following a string of filters and searches it is displayed the data related with the assessment of the health effects. This process will be described later.

To obtain this assessment in the quicker way ARIES is physically supported by an informatic system. However ARIES's informatic support is a data base type, its aim is not to be just a tool to store information; in fact its file structure design is not the best for this idea. In this regard, as we said above, ARIES came up as a strategy to resolve in a rational, systematic and efficient way, the health effects assessment problem.

All along the development of the methodology and the tool, we have been considering both as very close dependant. This is the reason why when we describe ARIES we do it thinking as a methodology to be performanced by an informatic system, and sometimes it is difficult

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[1] Aplicación a Riesgos Industriales para la valoración de los Efectos sobre la Salud (Application to Industrial Risk for Health Effects Assessment)

to describe the methodology or the tool separately because both have been designed in function of the other.

ARIES: GENERAL DESCRIPTION

The aim of this application is to analyze the existing information, select and apply it for the asssessment of the health effects caused by an accidental exposure. As we comented above the effects caused by a chemical differs extremely as a function of different parameters principally with the product concentration and the exposure time. In this sense, for example, some products will produce an immediate damage on human health if the concentration is high but, once overcome the exposure, will not be defered effects; some could be that, even though there were not acute exposure, generate medium term effects; from others, it is unknown the concentration begining from it could appear chronic effects; and as these cases related above we could find many different cases.

When there is an accidental release of a chemical we face a special exposure situation. That is: the concentration is going to be high (toxic dose) and the exposure is going to be more or less punctual. In case of an accidental release the first problem is to resolve the acute toxicity. Once overcome this phase gains priority the medium and the long term effects.

There exists two different stages we have developed for the assessment. In general terms we can describe the first approach as Quantitative and the second one as Qualitative.

The first stage corresponds to the one where the concentration of the toxic chemical released is numerically analyzed in order to define different ranges of danger and effects. Following with the process and once finished the first stage ARIES develops the second one that consists on the selection of the data that can support the assessment.

Now we enter to explain the whole process: For each chemical exist certain exposure values established in accordance with different criteria, as workers exposure values, lethal doses, dangerous dose, etc. Each of these values have a different meaning in accordance with the

time of exposure, the concentration and the expected effect. ARIES gather all the existing values and apply them to the assessment. Before the application of this process, all the values have been analyzed in order to select the adequate ones to be applied to the assessment. Also and depending on the values, is necessary applicate different sort of treatments as those refered with interspecific extrapolations, dose absorbed, uncertainty factors, etc. Once ARIES realize this treatment, calculates the absorbed dose for the external concentration and that time of exposure, and compares the result with the other values and displays the evaluation of this situation.

The exposure values serie to which it is compared the external concentration includes all those values, belonging to each product, selected to be used in this process. In this serie we have included two sort of values:

a) *Standard values*: those that have a previous established meaning (as LD, IDLH, etc). (See Anexe I).

b) *Particular values*: those obtained from specific situations (from workers punctual exposures, accidents, epidemiological studies, etc.)

Next, we explain the assesment process of ARIES; in order to simplify we only use the standard values.

In case where the scattering pathway were the atmosphere, the exposure values that we use to compare with the concentration of the toxic chemical released are the followings: TLV-TWA, TLV-STEL, TLV-C, TLV-excursion, NOAEL, LOAEL, IDLH, CLm y CL50 (See definitions in Anexe I). It is necessary analyze the significance of these values in order to do its correct application to the assessment.

The TLV values (Threshold Limit Value) are established values for workers exposition, and they can be used on the comparative process. Within these labour exposure limits, there are different categories (TWA, STEL, C, excursion) that have a particular meaning. When the

atmospheric concentration of the chemical product released is the same or smaller than TLV-TWA, we can supose that it will not produce adverse effect in the population. That is because this value, TLV-TWA, is that to which a worker can be exposed during his working life without having generated any adverse effect.

TLV-STEL and TLV-excursion are concentrations that ones overcome could start to induce, from physical irritation to physical impairment. Consequently, it should start to take precaution in order to prevent the adverse effects.

TLV-C exists for those chemicals considered very irritants or asfixiants. Therefore, when external concentration exceeds TLV-C value, a potential hazard from that substance is presumed to exist and in case of accident it could delimit the first zone of danger.

The NOAEL (No-Observed-Adverse-Effect-Level) and LOAEL (Lowest-Observed-Adverse-Effect-Level) values are established by the Environmental Protection Agency from the United States, and these values point out the limits derivated from its significance.

The IDLH (Immediately Dangerous for Life and Health) values indicate the concentration since and after a time exposure of 30 minutes there is a danger for life and health. This value is established by NIOSH (National Institute for Occupational Safety and Health) and must be analyze for each product. It is necessary know what kind of effect is expected: if it is a reversible or irreversible health effect, or a life effect. Another thing to have into account in the use of this value is that is not established when the product is considered carcinogenic. In these cases is necessary know if the product either generate another toxic effect (in short and medium term) different from carcinogenesis.

LC50 values (Lethal Concentration 50%) are established values that can be used to assess the toxicity level of products (Anexe IV 82/501/EEC) and for this reason is a value that it should exist for all the products. Due to the possibility to have this value, and considering that there are not many exposure values for chemical products, we cannot reject its application (after the necessary extrapolation to humans) to the assessment process. Obviously, in case this concentration is overcome the expected effect should be a catastrophe,

however and in case the concentration does not arrive to that value it does not signify that nothing extremely dangerous serious is going to happen. LCm values (Lethal Concentration Minimum), which indicate the concentration from which mortality can be expected are also used in the process.

It is necessary point out that except TLV's and IDLH's the rest of values usually come from the results on animal research and for this reason the values that are going to be used in the assessment process need to be extrapolated to human beings. Consequently, its use requires a detailed analysis not only about experimental conditions but also about the type of extrapolation to be used (including the possibility to realize or not this extrapolation). As we have already mentioned ARIES works with all the values comparing the equivalent dose inhaled for each exposure time and the other values.

As we mentioned, if there are "*particular values*" (b) as those from epidemiological studies, accidents, other researchs, etc., they are used as well in the assessment.

The first step that face ARIES is the way to standarized all these values with the objetive to be compared between them. For this aim ARIES calculate the inhaled dose absorbed all along the time of exposure for each value. This gives a board of values with a specific meaning among it can be located the "real" dose inhaled by a person exposed to a certain concentration of the chemical accidentally released. Depending of the location of this value and on the meaning of the values that sorrounds this one it can be displayed a first approach of the expected danger.

After this step, ARIES develops the qualitative process selecting the data refered to the effects expected from an acute exposure considering the entry route. In this phase the information selected is about acute toxicity and about the immediate and differed effects. In this case if the information is not enough it appears the existing one about other sorts of exposure, as that for workers exposure for example. In the latter case the data is considered with care because these effects are caused by a continuous exposure to dose relatively low (situation that differs a lot from the one produced by an accidental release).

Once reviewed the human data and if the information still being scarce ARIES goes to more specific information about experimental data. Then, ARIES goes to animals data. The complete analysis of all the selected information through this search, let identify the expected health effects.

ARIES: CONTENTS, STRUCTURE AND INFORMATIC SUPPORT

One of the first steps for the assessment is to define those aspects needed for it. We have already comented that the information differs not only in quantitative but also in qualitative aspects. Now then, when we defined the items we had to consider the necessity to cover the absence of specific human data. With this idea we had to:

- Select aspects, not only directly related with human beings but, related with other subjects that complete and complement the absence of human data.

- Define and structure the subjects in a specific way in order to facilitate the direct selection in those cases where the amount of information is big.

ARIES's content is defined in accordance to the necessity of define concret aspects in order to cover the data gap. As we have said, to achieve the assessment is necessary consider whatever human data available. In those cases where this is not enough is necessary consider data from laboratory animals, metabolism of the product, etc. If afterwards there is still no relevant information it can be consulted data from similar chemicals.

ARIES is designed not just with the aim of storing information but in order to manage it in a dynamic and selective way. When we proposed ARIES as an alternative to the absence of quantitative models, we thought in ARIES as a process very close dependant with an informatic system in order to obtain the quickest assessment. Because of this, ARIES's content is structured in such way that its applications to the informatic tool is almost direct.

According with the narrow relation between ARIES methodology and tool, ARIES's content is structured as a data base where the related data are gathered in files, and the specific aspects defined in fields.

On Figure 1 we can see the abstract structure of ARIES. The terms framed are those refered to the files assigned in order to that sort of information. Terms without frame correspond to fields that belong to the "Toxicological summary" file. All the files are interconected through specific fields in such way that the system goes from one to another to complete the process.

This structure, from an informatic point of view, permits: (I) develop a dynamic and flexible system, (II) facilitate the conexion between sections, (III) know the existence or absence of data, and (IV) direct access to wanted information.

The files and fields considered in ARIES are those which we considered as necessaries to have into account in a database to assess the effects. In ARIES the fields assigned to each file depend on the information contained in itselves.

All the data are structured in these files:

1 Toxicological summary
2 Human toxicity
3 Animal toxicity
4 Long term and hereditary effects
5 Metabolism
6 Exposure values
7 Toxicity and Environment
8 Test

As we have mentioned the data have been grouped depending on its content. This means that the specific information described by each field has been grouped into specific files. All the files have a common field named "Index" which contains a number identificator called the

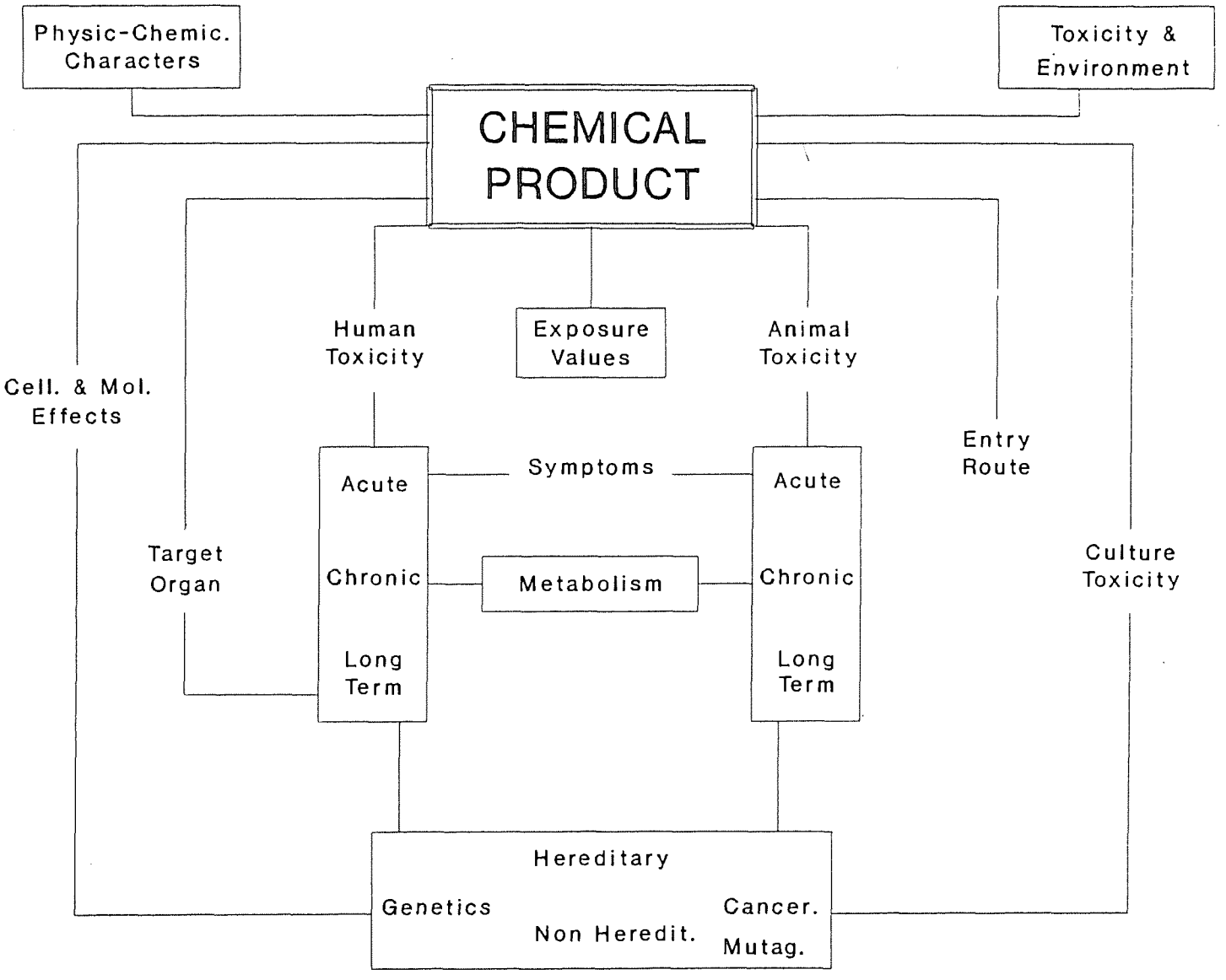
Physic-Chemic. Characters
Toxicity & Environment
CHEMICAL PRODUCT
Human Toxicity
Exposure Values
Animal Toxicity
Cell. & Mol. Effects
Entry Route
Acute
Symptoms
Acute
Target Organ
Chronic
Metabolism
Chronic
Culture Toxicity
Long Term
Long Term
Hereditary
Genetics
Cancer.
Non Heredit.
Mutag.

Figure 1

ARIES Number. This field is the link between all the files. We have chosen this identificator because prevents from confuse when is used the chemical name as identificator and is a good key to identify the chemical in the informatic application.

Following we describe the content of each file and its specific structure.

1.- Toxicological Summary

The sort of information gathered in this file corresponds to general information about the toxicity of the chemical. These data are a summary of the relevant aspects contained in other files where the information is more extense and detailed. In this file the data show general information about what is known about the toxicity of the chemical.

In this file there are two fields refered to the chemical identification: one is the ARIES Number and the other is the name as it appears in the Directive.

The fields "Entry route" and "Target system" are refered to the most common entry route in case of an accident and the organic system first affected by an acute exposure.

Other field established is the "toxicity level" according to the table that appears in Anexe IV in the 82/501 Directive. We have numbered these rates from one to three as a function to its decreasing toxicity level.

There are also fields that resume the existing information about acute toxicity of the chemical for humans and experimental animals.

Other fields contain a summary of the experimental results obtained in bacterial and cellular cultures (only filled if there is no information on humans nor experimental animals).

There is a specific field that indicates if the product cause or is suspected to cause any cellular or molecular damage, pointing out if the effect is carcinogenic, mutagenic, teratogenic, etc.

In the following table we can see the differents fields considered in this file:

FIELD	CONTENT
INDEX	ARIES Number
NAME	Product name as appears in the Directive 501/82/EEC.
ENTRY ROUTE	Inhalation, ingestion,contact
TOXICITY LEVEL	As table in Anexe IV within Directive 501/82/EEC.
TARGET SYSTEM	Organic systems affected by an acute toxicity.
BACTERIAL AND CELLULAR CULTURES	Summary of the results in these sort of experiments.
ANIMALS TOXICITY	Summary of toxic effects detected in experimental animals.
HUMANS TOXICITY	Summary of toxic effects in humans.
CELL-MOL. EFFECTS	Summary of the possible cellular and molecular effects.

FILE 1: Toxicological Summary

2.- Human Toxicity

All the information about human toxicity is gathered in this file, although our goal is to know the health effects produced at short, medium and long term, by punctual (or short time) exposure to relatively high concentrations.

One of the biggest problems of the existing information about human effects is its diversity not only in relation with the type of exposure but also with the concentration.

Most of the information comes from results on workers. This sort of information is a very specific one because, excluding the accidental exposures, the effects are caused by a continuous exposure to relatively low concentrations. This situation differs a lot from the existing in case of an accidental release, and these data refered to effects in workers have to be considered with care. Although is not the more accurate data for toxicity assessment, in many cases is the only information about the chemical toxicity and we can not rejected it.

Considering the questions refered above we have structured the information as a function of: route of entry, kind of exposure and immediate and differed effects in all the cases.

In the next Table we refer the fields considered in this file and its content.

FIELD	CONTENT
INDEX	ARIES Number
ACUTE TOXICITY	Toxicity level and the most common entry route
HAG_I_INH	Immediate effects by acute exposure (Inhalation)
HAG_D_INH	Difered effects by acute exposure (Inhalation)
HAG_I_C	Immediate effects by acute exposure (Contact)
HAG_D_C	Difered effects by acute exposure (Contact)
HAG_I_ING	Immediate effects by acute exposure (Ingestion)
HAG_D_ING	Difered effects by acute exposure (Ingestion)
HCR_INH	Effects by chronic exposure (Inhalation)
HCR_C	Effects by chronic exposure (Contact)
HCR_ING	Effects by chronic exposure (Ingestion)
CELL-MOLECULAR HEREDITARY EFFECTS	Summary of the specific file
TARGET ORGAN	Organs affected
METABOL_H	Indicates if exists mathematical models of metabolical behaviour or specific information in the corresponding file

FILE 2: Human Toxicity

3. Animal Toxicity

This file contains all the existing information about animals toxicity. As we have said many times, the existing information about the human toxicity of the chemicals is very scarce and therefore is necesary consider other information sources, as in this case animals, to fill the gapped knowledge.

The structure of this file is quite similar to the human file. This similarity between humans and animals files facilitate the conexion related to specific aspects between both files. This sort of information, in case there no exist human data, give a first approach to expected effects. Obviously, this does not mean that the information can be extrapolated to humans directly.

There is also a special field for other entry routes as those used in experiments: intraperitoneal, intramuscular, intratracheal, etc.

The data within these fields indicates the animal used in the experiment and a summary of the results obtained. The specific conditions of the experiments will be included in the TEST FILE.

The file is structured in the following way:

FIELD	CONTENT
INDEX	ARIES Number
TOX_AGU_A	Toxicity level and the most common entry route.
AAG_I_INH	Immediate effects by acute exposure (Inhalation)
AAG_D_INH	Difered effects by acute exposure (Inhalation)
AAG_I_C	Immediate effects by acute exposure (Contact)
AAG_D_C	Difered effects by acute exposure (Contact)
AAG_I_ING	Immediate effects by acute exposure (Ingestion)
AAG_D_ING	Difered effects by acute exposure (Ingestion)
ACR_INH	Effects by chronic exposure (Inhalation)
ACR_C	Effects by chronic exposure (Contact)
ACR_ING	Effects by chronic exposure (Ingestion)
AEFC_EXPER	Effects under specific conditions.
AEFEC_LARG	Summary of the file of cel.-molecular and hereditary effects.
AORG_DIANA	Organs affected.
METABOLISM	Indicates if exists mathematical models of metabolical behaviour or specific information in the corresponding file.

FILE 3: Animal Toxicity

4.- Long Term & Hereditary Effects

These effects are those considered long term, hereditary and embriotoxic effects. The data considered in this file comes from different sources: epidemiological studies, experimental data from long-term test in laboratory animals and results obtained from cellular and bacterial cultures.

Epidemiological data gives a causal relation between chemical product and effect, but does not give a defined exposure- effect relation. Data from test in laboratory animals present all the inconvenience we already know about extrapolation to humans.

The fields considered are those refered to carcinogenicity, genotoxicity and reproductive effects. The data within these fields should contain a summary of the results and conclusions obtained in the experiments. The specific conditions of the experiments would be included in the TEST FILE.

The field carcinogenicity indicates if the chemical is considered carcinogenic from what IARC (International Agency for Research on Cancer) says. It defines three categories:

Category 1: Carcinogenic to humans.
Category 2: Probably carcinogenic to human.
Category 3: Cannot be clasified as to its carcinogenicity to humans.

There are other categories established by other research agencies as NTP (National Toxicology Program, USA) which defines five categories, and USEPA (United States Environmental Protection Agency) which also defines five different categories.

If the data come from one of these sources it should be indicated to which category the chemical belongs and its significance. If the chemical has not been included in these categories it should be indicated all the relevant data about the experiment from which comes

the information.

In this file there are also other fields refered to the genotoxicity of the chemical, as those as "Chromosomic effects" and "Mutagenicity".

The field reproductive effects indicates if the chemical affects reproduction. It is specified if the effect is teratogenic, embriotoxic or reproductive.

The structure of the file is as follows:

FIELD	CONTENT
INDEX	ARIES Number
CARCINOGENICITY	As the IARC classification.
CHROMS. EFFECTS	Summary of experiments and results.
MUTAGENICITY	Summary of experiments and results.
REPRODUCT. EFFECTS	If the product causes teratogenicity, embriotoxicity or reproductive effects.

FILE 4: Long term and hereditary effects

5.- Metabolism

This file gather all the information refered to the metabolism of the chemical product. It is a common file for humans and animals but the data are specified to which they belong.

The information contained in this file is necessary to understand both, the toxicological action of the chemical and the different behaviour among species. Consequently, it will facilitate the data and the information needed to scale the results obtained in animals to humans. It will also explain the differents effects generated by products considered chemically similar, or the same effects induced by different chemicals.

We have structured the fields depending on the different aspects of the metabolism: Absorption, Distribution/ Accumulation, Excretion, Metabolic pathways, Metabolites.

The field "Models" indicates if there exist any mathematical models applied to metabolic behaviour of the chemical or any other sort of models.

FIELD	CONTENT
INDEX	ARIES Number
TARGET ORGANS	Organs where there is an adverse effect or there is a high or abnormal accumulation.
ABSORPTION	Absorption of the chemical through the different entry routes.
DISTRIBUTION /ACCUMULATION	Distribution through the organism and places where is retained during significant periods of time.
TRANSFORMATION	How the chemical is transformed from its original form to some other compound or series of compounds.
METABOLITES	Intermediate products generated by the product during its metabolism.
EXCRETION	Ways of excretion.
METAB. PATHWAYS	Indicates if the product is metabolized through a specific metabolic pathway.
MODELS	If exist mathematical model applied to the metabolic behaviour.
RESIDENCE TIME	Biological halftime:(hours,days, months and years).

FILE 7: Metabolism

6.- Exposure Values

In this file we have defined the fields for the exposure values we consider adecuate for an exposure asessment. We have considered two kinds of values: "standards" and "particular values". We call "standard" to those values established and accepted by international agencies. We consider "particular values" those that proceed from varied and differents sources as epidemiological data, accidents, etc.

The structure for this file has into account either "standard" and "particular values". In the following structure we named the fields and the significance of the abbreviation for "standard" values. We leave six fields for particular values, considering it can exist more or less than this quantity. These fields have an associated text field where is explained the specific meaning of the value.

All these values are given in mg/m3 or ppm.

FIELD	CONTENT
INDEX	ARIES Number
TLV-TWA	Threshold Limit Value- Time Weighted Average
TLV-STEL	Threshold Limit Value- Short Term Exposure Limit
TLV-C	Threshold Limit Value- Ceiling
TLV-Excursion	Just in case there no exist TLV-STEL
NOAEL	No Observed Adverse Effect Level
LOAEL	Lowest observed Adverse Effect Level
IDLH	Immediately dangerous for life or health
LD50	Lethal Dose for the 50%.
LDm	Minimal Lethal Dose.
LC50	Lethal Concentration for the 50%
LCm	Minimal Lethal Concentration dose
PART-VAL-1	Particular value
PART-VAL-1-M	Meaning of this value
:	
:	
PART-VAL-6	Particular value
PART-VAL-6-m	Meaning of this value

FILE 6: Exposure Values

7.- Toxicity and Environment

This file gather genera! information related with environmental fate and concentrations of the chemical product in the abiotic media (atmosphere, water and air) and the effects on the biotic media (flora and fauna). There are some fields refered to "environmental values" where there are the concentrations standards considered dangerous: toxic concentrations, environmental concentrations, Toxic doses, etc.

FIELD	CONTENT
INDEX	ARIES Number
BIOTA	Effects on the biota
WATER	Concentration and fate.
ATMOSPHERE	Concentration and fate.
SOIL	Concentration and fate.
ECOTOXIC VAL	Environmental quality values.
:	
:	
ADI	Acceptable daily intake

FILE 7: Toxicity and Environment

8.- Test

This file gather all the existing experimental results that support part of the information

included in the files: human toxicity, animal toxicity, cellular and molecular effects, metabolism and exposure values.

FIELD	CONTENT
INDEX	ARIES Number
ENDPOINTS	Classical toxicity, cellular toxicity, genotoxicity.
TEST	LD50, LC50, absoption, transport, etc.
ORGANISM	Procariotes, lower eucariotes, higher eucariotes.
RESULTS	Summary of the results.
EXPOSURE	Acute, Chronic & Subchronic.
ROUTE	Inhalation, ingestion, dermal, intraqueal, intravenous, etc.
DOSES	
MEASURE	Moment where the effect is observed.
DOSE RATE	Frequency.
SPECIE	Human, rat, mouse, etc.
SEX	Male or female.
NUMBER	Number of individuals exposed in the experiment.
AGE	
KIND OF STUDY	Laboratory, working place, authopsies..
TARGET ORGAN	Organ affected by the exposure.
DISCUSSION	Discussion of the results.

FILE 8: Test

There are fields that indicates the sort of test: Endpoints, Test, Organism and evaluation. Others are refered to its description: Exposure, Route, Dose, Dose Ratio, Specie, Sex, Number of exposed individuals and Age. The fields Kind of study describes the test conditions. Target organ, and Discussion explain the conclusions.

ARIES: ASSESSMENT PROCESS

Figure 2 shows how ARIES works. The first stage it is directed to identify if the product is contained in ARIES. The search process is based on the identification number. This system is direct and prevents from possibles mistakes when the search is made through the products name since there are many synonyms for each product and to realize this search properly it should be considered all of them. Once the product is located, ARIES shows a report with general toxicological data as: chemical product, formule, toxicity level, dangerous labels, etc. (The information contained in the file "Toxicoloxical summary" of ARIES). After this information it appears a menu with these options: GROUPS, DATA BASE, and ASSESSMENT.

The option DATA BASE, corresponds to a conventional consult where the process consists on selecting the file to which is desired more information. The data is displayed in accordance with the different fields in the files described in section "ARIES: Contents, structure and informatic support". As this option of consult is a very common one to use we do not explain it with further details.

The option GROUPS shows a board with a list of labels that identify or classify the products in order to different criterion (toxicity level, sort of effect, chemical behaviour, structure-activity relationship, etc.). This panel permits have a quick idea of the sort of product we are working with.

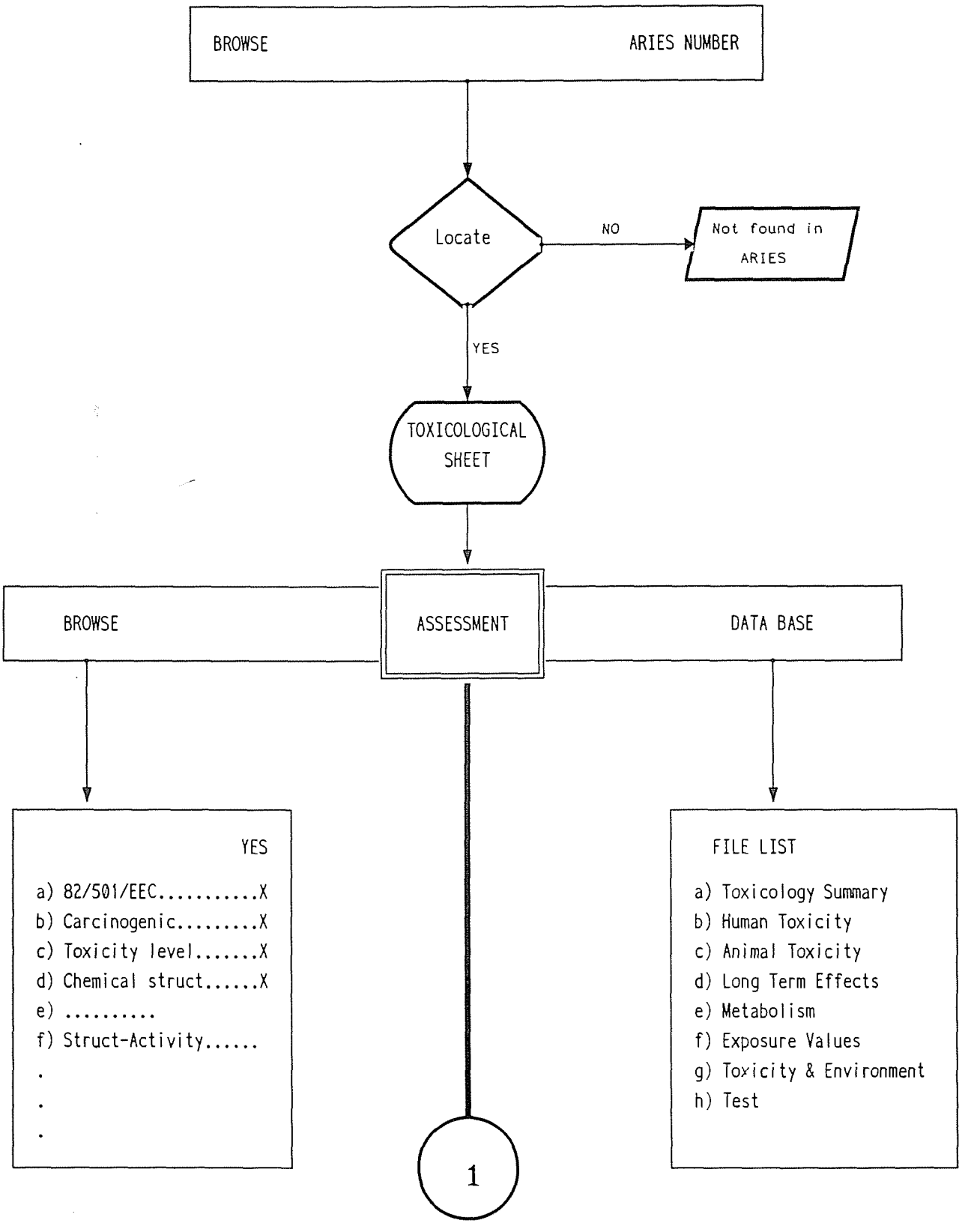

Figure 2: ARIES Flow diagram

Potentially, in the future this option could contain the information needed to group the product with those to which share characteristics (depending on the characteristic defined by the category); in such way the expected behaviour of the product should be that defined for the group to which it belongs and this could contribute with complementary information about the product.

The option ASSESSMENT is definitively the main aspect of ARIES and we follow to explain it with detail.

The aim of this application is to analyze and asssess the existing information related to health effects caused by an accidental exposure. As we comented above the effects caused by a chemical differs extremely as a function of different parameters such as the product concentration and the exposure time.

Figure 3 shows the flow diagram of how the system works for the effects assessment, the upper zone corresponds to the application refered to risk identification and quantitative assessment.

Before going further on the analysis, ARIES works in order to exclude the non toxicological risk; in our case we consider as risk the product toxicity derived from its accidental release, no considering in the begining those cases where the potential risk is just the explosion or fire (in these cases the toxicity risk should be on the subproducts generated by the explosion or fire).

Following with the flow diagram, and once identified the toxicological risk, ARIES asks for the scattering pathway (aquatic or atmospheric). From this point the methodology is equivalent but applied specifically to each one.

In the next stage ARIES asks for the concentration in the water or air. With this concentration and through a comparative analysis between this value and the exposure values within ARIES, we arrive to the identification of the existence or non-existence of toxicity hazards.

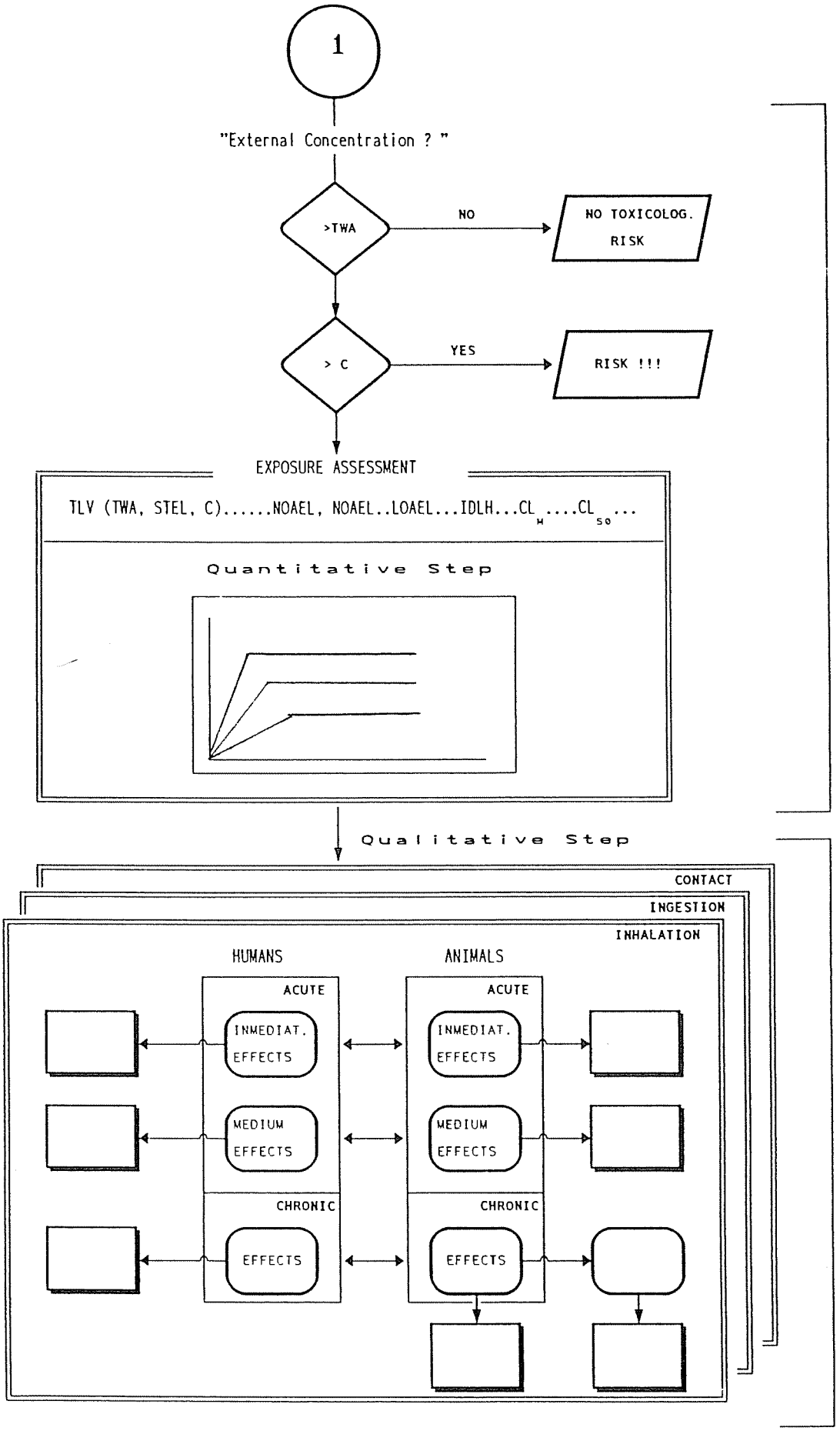

Figure 3: ARIES Assessment

The exposure values serie to which it is be compared the external concentration is formed with all those values, belonging to each product, selected and transformed to be applied in this process.

With all these values (see section " ARIES: General description") it is possible to establish a concentration gradation to which it can be compared the external concentration of the chemical released to identify the risk. Although this scale and its associated risks are not necessarily the same for all the products in the assesment process, one simple example could be the one shown in Table 1.

CONCENTRATION LOWER THAN:	INITIAL ASSESSMENT
TLV-TWA	No adverse effects expected
NOAEL (*)	No adverse effects expected Watch concentration!!
TLV-STEL TLV-excursion	Take precautions if concentration reach these values !
LOAEL (*)	It could start adverse effects. Precaution!!
IDLH	You have 30 m. to act with security.
LDm (*)	DEATH danger. SERIOUS ACCIDENT!
DL50 (*)	CATASTROPHE!! It can be a mortality near to 50%.

(*) Extrapolated to human beings

TABLE 1

As we comented, the atmospheric concentration of the chemical product would be compared with the existing exposure values contained in ARIES. As a function of the relative position of this concentration in the scale of values, the danger should be higher or lower, and ARIES would display the corresponding risk message. Furthermore, crossing the values scale with a Geographical dispersion map of the released product it could be possible to delimit the different hazardous areas.

At the first moment ARIES locates the external concentration between the differents exposure values depending on its own value. Then applies the different treatments for these values (extrapolation, dose inhaled..) and displays new panels where is calculated the development of the inhaled dose at different periods of time (Report: "ARIES Assessment" in progress). This process is applied to all the values selected and in these new scales the dose inhaled, because of the exposure time and the external concentration, is located between the other values to see its risk meaning changes in function of time.

On Figure 4 we have an example with Ammonia. The External Concentration, as first step, should be located in the board displayed in the lower side of the figure.

When the dispersion of the chemical is through the aquatic pathaway the assessment process would be similar but using different values as: environmental concentration, Lethal Concentrations, daily intake, etc.

Effects Assessment

Once identified that there exist risk, ARIES goes to the effects assessment stage (Figure 3) where the system works in a particular way for each product and depending whether the entry route were oral (aquatic dispersion pathway) or respiratory (atmospheric dispersion pathway).

In general, the process is the following: It enters in the file with information about human

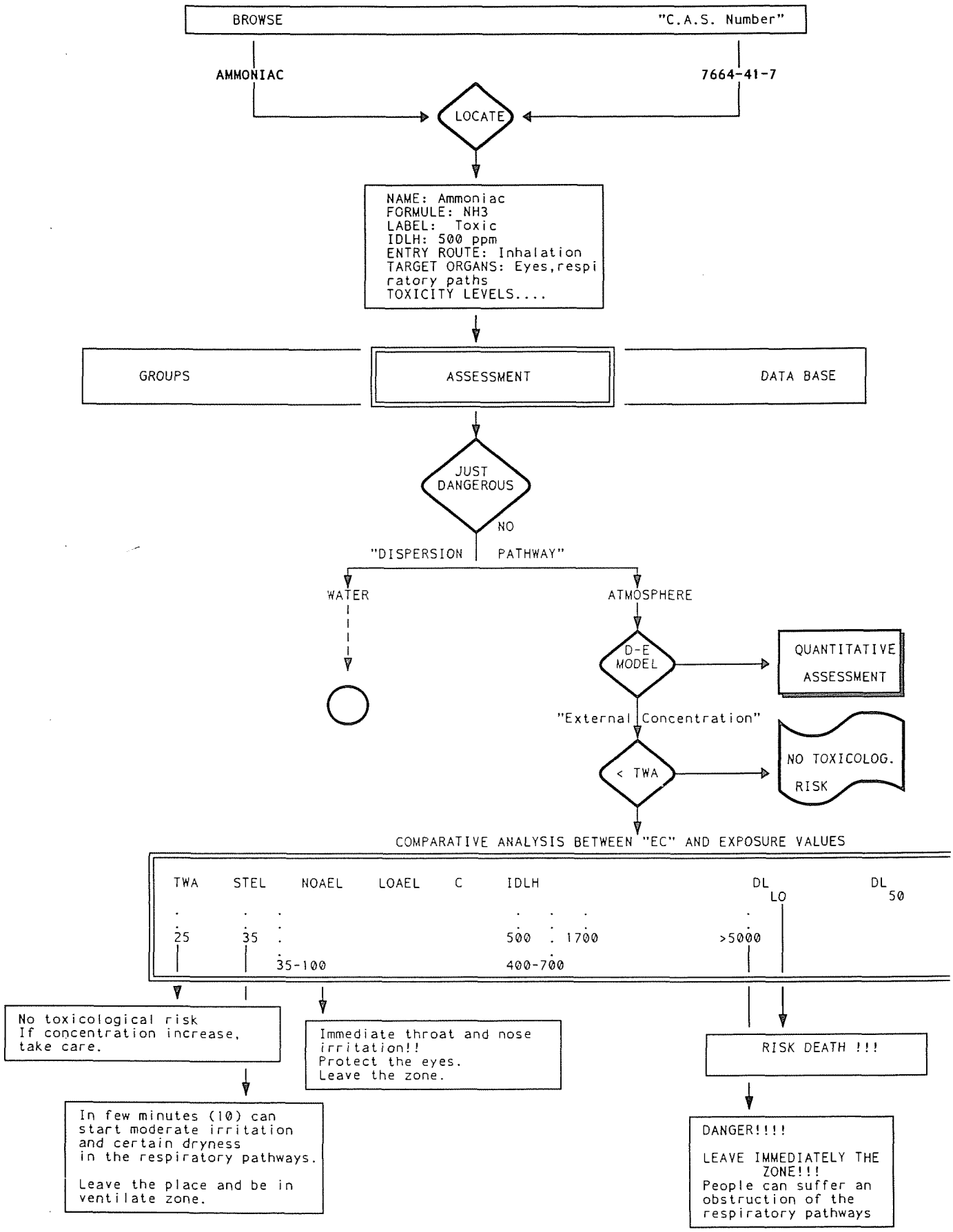

Figure 4: Risk Identification applied to Ammoniac

toxicity and looks for those data related with effects produced in short, medium and long term by an acute exposure. In case, this information were enough, there is an information output with the expected effects and some precautions to consider. In case this information were not enough, the system goes first, to other fields related with the expected human efects induced by non-acute exposure and then, to complementary files (as animal toxicity, metabolism, Cellular and molecular effects...) in order to obtain the maximun data to display to the user. In fact, the information displayed to the user is the one selected through a sequence and system of filters, where it is indicated the expected effects.

This is, in general terms, the total process that would develops ARIES in order to assess the health effects induced by the accidental release of a chemical. We can divide this process in two different stages: the first corresponds to the initial risk identification through the comparative analysis among the external concentration and the existing exposures values; and the second stage corresponds to that related to effects assessment through the qualitative analysis of the information.

The first stage of the assessmet works with quantitatives data and the development of this stage not only depends on the disponibility of these values but on the particular analysis of each one in order to its application to risk identification, because it is evident that each standard value has its own significance but we cannot forget that ARIES applies them in other functions that differs from its strict meaning.

The second stage of the process consist on a search string and a system of filters common for all of the products, although the displayed information is particular for each case. Consequently it requires an specific analysis for each chemical.

Even though this two stages are realized each time, due to the information lack, we can find this situations: (i) products that have not sufficient exposure values; (ii) products with no sufficient toxicological information to realize a complete assessment.

In the first case, ARIES goes directly to the qualitative analysis of the information, pointing out the absence of quantitative data that allows a first risk analysis.

In the second case the system advices that the data are not enough to realize the assessment but this information can be completed looking for information in other products or groups of products (specified by ARIES within GROUPS option) that for its similarity with the group selected can offer an idea of the expected effects.

ARIES SOFTWARE

As we have described, all the data that ARIES contains are stored as a data base in the fields and files described in "ARIES structure". The structure explained describes the different aspects considered necessaries for the process and the way we have grouped these data.

We have already described how ARIES works with all the contained data. The informatic structure of the different files is similar to the one described in the section refered to the description of each file, in order to do its direct application to the informatic system.

The informatic tool use is the software "dBase IV dv". It works with a dbase/SQL language. dBase IV lets design not just the different files but also lets manage the data. One of the best advantage of this software is the fact that let create a relational database and programme the application for the management of the data and the development of the assessment. On the other hand the application has been designed taking into account its capacity to be linked with the differents models that progresively will be incorporated to ARIES.

Until now we have designed all the files having into account the way we want to use these data and have created the fields in order to its specific use in the Application. We have started to design and develop the Application. At this moment is programmed a first prototype of ARIES that can be executed in PC's and it can run for almost twenty products

The Project Health Effects, within Industrial Risk Program, continue researching about the treatment of the exposure values defined in the text, and other related questions, in order to obtain a direct answer about dose-effect, and the different results are and will be incorporated to ARIES as they are obtained.

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ANEXE I

TLV-TWA : (Threshold Limit Value- Time Weighted Average) The time-weighted average concentration for a normal 8-hour work-day and a 40-hour workweek, to which nearly all workers may be repeatedly exposed, day after day, without adverse effect.

TLV-STEL:(Threshold Limit Value- Short Term Exposure Limit) The concentration to which workers can be exposed continouosly for a short period of time without suffering from 1) irritation, 2) chronic or irreversible tissue damage, or 3) narcosis or sufficient degree to increase the likelihood of accidental injury, impair self-rescue or materially reduce work efficiency, and provided that the daily TLV-TWA is not exceeded.

TLV-C: (Threshold Limit Value- Ceiling) The concentration that should not be exceeded during any part of the working exposure.

NOAEL: No Observed Adverse Effect Level. The highest dose in an experiment which did not produce an observable adverse effect.

LOAEL: Lowest Observed Adverse Effect Level. The lowest dose in an experiment which produced an observable adverse effect.

IDLH: Immediately dangerous to life or health concentration; represents the maximum level from which one could escape within 30 minutes without any escape-impairing symptoms or any irreversible health effects.

LD50: The dose of a chemical taken by mouth or absorbed by the skin which is expected to cause death in 50 percent of the test animals so treated.

LDm: Minimum Lethal Dose

LC50: The concentration of a chemical in air or water which is expected to cause death in 50 percent of test animals living in that air or water.

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40 pp.; 4 Fig.; 13 Fig.

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The system starts the assessment process with values of external concentrations which are processed, together with different exposure values (existing for humans and scaled up from animals), as inputs for different kinds of models. From these, and other physiological values ARIES calculates the inhaled equivalent doses and the expected associated effects as a function of the exposure times.

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Once overcome this first step, ARIES is complemented with an additional system that executes the selection of relevant information from toxicological data bases (qualitative phase). The system works applying a string of filters and searches that displays selected information, giving an additional support to the assessment.

Both steps, just refered, are integrated into a logical informatic support. The informatic code is developed in dbase language even for the design of the procedure as for the mathematical models linked to the system (extrapolation, dose inhaled models, etc.) to execute the numerical analisys of the assessment. The system has been designed in order to include progressively new chemicals and the improvements obtained in the development of mathematical models related with dose-effect relationships. At this moment, is programmed a first prototype of ARIES that can be executed in PC's and it can run for several products.

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El sistema ARIES comienza el proceso a partir de las concentraciones externas a las que está expuesta la población tras el accidente. Este valor se procesa junto con valores de exposición (procedentes de humanos y de experimentación en animales) como entradas de los modelos que se aplican en la

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Una vez ejecutada esta primera fase, ARIES pasa a una fase complementaria de carácter cualitativo en donde a través de una secuencia específica de búsquedas y filtros, se selecciona, de una base de datos toxicológica, la información relevante que apoya la valoración cuantitativa realizada en la fase anterior.

Las dos etapas indicadas están integradas en un soporte lógico informático. El lenguaje informático utilizado tanto para el desarrollo de la aplicación como para la integración de los modelos matemáticos aplicados a la valoración numérica de la exposición (extrapolación, cálculo de dosis incorporada, etc.) es el lenguaje dbase. La aplicación ha sido diseñada de forma que acepte la incorporación de nuevos productos químicos o/y los progresos obtenidos del desarrollo de los modelos de cálculo que relacionan la dosis con los efectos producidos por la exposición. Actualmente se dispone de un primer prototipo de ARIES que ejecuta la valoración de la exposición en PC's para una serie de productos.

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valoración. A partir de estos datos y junto con datos de carácter fisiológico, ARIES calcula la dosis incorporada y halla el efecto esperado sobre la salud, en función del tiempo de exposición al que se ha estado sometido.

Una vez ejecutada esta primera fase, ARIES pasa a una fase complementaria de carácter cualitativo en donde a través de una secuencia específica de búsquedas y filtros, se selecciona, de una base de datos toxicológica, la información relevante que apoya la valoración cuantitativa realizada en la fase anterior.

Las dos etapas indicadas están integradas en un soporte lógico informático. El lenguaje informático utilizado tanto para el desarrollo de la aplicación como para la integración de los modelos matemáticos aplicados a la valoración numérica de la exposición (extrapolación, cálculo de dosis incorporada, etc.) es el lenguaje dbase. La aplicación ha sido diseñada de forma que acepte la incorporación de nuevos productos químicos o/y los progresos obtenidos del desarrollo de los modelos de cálculo que relacionan la dosis con los efectos producidos por la exposición. Actualmente se dispone de un primer prototipo de ARIES que ejecuta la valoración de la exposición en PC's para una serie de productos.

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