Flemish Cancer League

A critical view on the policies regarding cancer-related chemicals in our living environment

Executive summary

Research report – May 2012

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Executive Summary of the Report

A critical view on the policies regarding cancer-related chemicals in our living environment

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1. Introduction

Cancer-related chemical agents are present everywhere in our living environment. 'Cancer-related' does not only refer to chemicals classified as 'carcinogens', but also to substances for which there are strong indications that they (help to) cause cancer, like endocrine disrupting chemicals. They are used in many industrial sectors and in agricultural products and are also contained in household and other everyday products and objects. No need to say that humans should be exposed to the minimum and preferably not at all to these agents. In case of exposure, the risks must in any case be restricted as much as possible . This can be achieved, in the first place, by means of efficient regulations and policies.

The VLK report 'A critical view on the policies regarding cancer-related chemicals in our living environment'[1] takes a closer look at the policies and regulations of recent years. On 26 November 2005 the Vlaamse Liga tegen Kanker (VLK – Flemish Cancer League) organised the symposium "How carcinogenic is our environment?" The VLK together with national and international specialists tried to present a state of affairs with regard to the relation between the environment and cancer. At that time the VLK formulated ten recommendations for policy makers to reduce exposure to carcinogens in the environment. We wondered whether the policies and regulations have moved in the right direction since then.

In order to study our topic in more detail we have restricted the report to the evaluation of the policies and regulations with regard to cancer-related chemicals in two domains: chemicals governed by the REACH Regulation and the policies and new regulations with regard to plant protection products (agricultural pesticides) and biocides (non agricultural pesticides). A lot has changed in both domains since the VLK symposium. This allows us to take stock.

REACH – the European Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals – is in effect since 1 June 2007. The first deadline has already passed. We wondered how REACH has progressed and how its implementation has proceeded up to present. For pesticides (the collective name for plant protection products and biocides) new regulations (for plant protection products) and a directive (for pesticides) have come into effect in recent years. For biocides a new EU Regulation is almost ready. Our country must adhere to all of these. In addition, Belgium at a federal level and Flanders at a regional level have listed a number of priorities and took a number of policy measures.

In the first chapter of the report you can read that environmental pollution has been underestimated as a cause of cancer for a long time. However, there are more and more indications that pollution largely contributes to the development of cancer. There is still quite some scientific uncertainty about the exact impact of the environment on the development of cancer, but there are more than enough scientific insights which urge us to be cautious. Chapter 1 of the report gives a short overview of those uncertainties and scientific insights.

A policy that is only targeted at chemicals which are officially classified as carcinogenic is not enough. At the symposium the VLK called for two major policy principles to be taken into account as well: the principle of physical-chemical hygiene and the precautionary principle. According to the principle of

physical-chemical hygiene we should as much as possible restrict chemicals that are suspicious due to their intrinsic properties. The principle can be compared to the microbiological hygiene which was applied in the early twentieth century to push back infectious diseases. In the same way we now have to conduct a preventive policy for the chemicals in the environment. The precautionary principle states that scientific uncertainty may never be an excuse not to take measures. When there are enough reasons to assume that an activity or a product or substance can cause serious, irreversible damage to one's health or the environment, preventive measures must be taken. The measures must be cost-effective.

Both principles are required to reduce exposure to cancer-related agents in a fundamental way. In our evaluation we will be verifying to which extent these two policy principles have been taken into account.

2. REACH

On 1 June 2007 EC Regulation No 1907/2006 'concerning the Registration, Evaluation, Authorisation and Restriction of CHemicals (REACH), establishing a European Chemicals Agency' entered into force. The European Chemicals Agency, or ECHA, manages the entire REACH process and involves the member states and interested parties in it. The European Commission plays an important role in the decision-making as well.

REACH ensures that an estimated 30,000 chemicals will be **registered** by 2018. There are three major deadlines, depending on the production volume and the risk posed by the chemical substance. The deadline of 30 November 2010 – for the largest production volumes (1000 tonnes or more), carcinogenic, mutagenic or reprotoxic substances (CMR substances) in a production volume of 1 ton or more and substances which are very toxic to aquatic organisms in a production volume of 100 tonnes and more – has already expired. For the other substances there is time to register until the next deadlines: 31 May 2013 and 31 May 2018.

Beside registration, REACH also includes a **dossier and substance evaluation**. In addition, there is also a **candidate list of substances of very high concern**, which is updated twice a year and currently lists 73 substances. The list contains substances that are candidates for selection to be placed on annex XIV, which is the **list of substances subject to authorisation**. It will not be possible to market the annex XIV substances for a certain use without authorisation. S*ubstances of very high concern* (SVHCs) are substances identified as carcinogenic 1a or 1b, mutagenic 1a or 1b, toxic for reproduction 1a or 1b (CMR substances); as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or they are substances which are of 'equivalent concern', such as substances with endocrine disrupting properties or PBT/vPvB-like properties. For substances on the SVHC candidate list an **information duty** applies if the substance is present in an object (manufactured article) above a concentration limit of 0.1 percent weight by weight: the information about SVHCs in objects must systematically be made available to professional buyers and to consumers on request. In addition, there is a **notification duty to ECHA** itself for candidate substances present in objects which are produced or imported in a total amount of 1 tonne or more per year and which are also present in those objects above a concentration limit of 0.1 percent weight by weight. For more complex objects not all member states agree about how the 0.1 percent

concentration threshold must be calculated. Belgium, together with a number of other countries, belongs to the countries with a deviating opinion. They adhere to the definition of an object as defined in REACH. This definition stipulates that the object does not lose its function when included in a more complex whole of objects. This means for example that when an SVHC is present in car seat lining, the concentration threshold of an SVHC must in all cases (by the importer of the fabric, the car seat or the car) be calculated in the fabric (deviating opinion) and not in the car seat or the car (other EU countries). This allows us to know in more cases whether or not an object contains an SVHC.

If an unacceptable risk is related to the production, the use or marketing of a substance, the member state, or ECHA on behalf of the Commission, can submit a dossier for a restriction (ban) of that substance. The **restriction list** (Annex XVII) already contains a significant number of substances because it also contains all existing restrictions based on previous legislation.

For a more detailed state of affairs with regard to the REACH Regulation and its implementation we refer to the first part of chapter 2 of the VLK report. It covers all relevant policy levels: the European level (where the different REACH processes are discussed in more detail) and also the Belgian and Flemish level.

In Belgium the legal competencies with regard to REACH are not only distributed over several government departments, but over the federal level and the regions as well. That is why a cooperation agreement was concluded on 17 October 2011 which will enter into force upon approval of the respective parliaments. We also considered the activities of the industrial sector in Belgium to implement REACH to the greatest possible extent: in order to support the Flemish industry (and mainly SMEs) in the implementation of REACH and of the CLP Regulation (the new regulation for the classification, labelling and packaging of substances and mixtures), the Flemish wing of the multi-sector umbrella organisation essenscia has implemented assistance projects since the end of 2007. This was done under the name VLARIP, or Vlaanderens REACH Implementatie Projecten (Flanders REACH Implementation Projects).

Evaluation of five years of REACH

In the second part of chapter 2 we take stock of five years of REACH regulation. We provide a comprehensive overview of the benefits and shortcomings. We also sound out the vision of experts. Which conclusions can be drawn?

Benefits

REACH has led to **a completely new approach for the control of the production, the import and the use of chemical substances in the European Union**. The industry needs to collect and provide the necessary data to ensure the safe use of chemicals. 'No data, no market' is the principle. The chemical industry is required to provide basic health and safety information for all chemicals produced or traded in quantities of 1 tonne or more per year per producer or per importer, and this before they are marketed. The REACH Regulation also **explicitly refers to the precautionary principle**.

With REACH a system was set up for a **better control of substances of very high concern**. These substances of very high concern also include **substances with endocrine disrupting properties**, under the name of 'equivalent concern', although we have to wait for the final criteria and tests to better identify these substances. The candidate list of substances of very high concern is important too: the

assumption is that it will discourage companies to continue to use these substances. For some of these substances of very high concern an **explicit decision process** will be set up, **thanks to the authorisation procedure**, in which an assessment will be made of whether we really need the substance in question. With the REACH Regulation we see therefore a **shift from a purely risk-based system to a system which is partly based on the intrinsic hazardous properties of a substance**.

REACH **improves the access to information about chemicals as well**: there are new extended safety data sheets (with exposure scenarios), all information about chemicals is collected at a central location and most is non-confidential, general health and safety information is made available to the public in a central database, there is – under certain conditions – a duty of information to professional buyers and (on request) to consumers and a duty of notification to ECHA for substances in objects on the SVHC candidate list. Hopefully this better access to information also pays off for the authorities themselves.

REACH **is expected to have a positive impact on our health and the environment**. It will only become clear in a few years time whether this will actually be the case though.

If we look at the Belgian compliance with **REACH**, we have to conclude that **our small country is making good efforts**, but is not one of the lead runners. The **progressive standpoint** of Belgium, together with some other countries, with regard to the interpretation of what can be considered an object is indeed very positive. This progressive stand **makes sure that the SVHC substances on the candidate list will in more cases be subjected to a duty of notification**.

If we look at the industry, the VLARIP assistance projects of the multi-sector umbrella organisation essenscia are certainly worthy of mention. These projects are set up to support the Flemish industry in the implementation of the REACH and CLP Regulations.

Shortcomings

Despite the huge leap forward that has been made with REACH, there are still some major shortcomings:

The REACH Regulation, in its current form, is **much weaker than the draft versions**. It is indeed one of the most lobbied topics around. The current regulation is actually a compromise.

30,000 of the estimated 100,000 to 115,000 chemicals will be registered with REACH. **Substances which are produced or imported in volumes of less than 1 tonne do not have to be registered under REACH.** Therefore, many substances are not covered by REACH.

Only for volumes exceeding 10 tonnes a chemical safety report must be provided. Between 1 and 10 tonnes only a technical file is required, with a limited number of data.

Substitution is not necessary in all cases where a safer alternative is available. We can also ask ourselves if an adequate control of substances of very high concern is really possible, especially when considering the entire life cycle. Adequate control is based on the assumption that there is an acceptable risk, or a safety threshold which – if not exceeded – guarantees that there will be no harmful effects and that regulators and industry can determine acceptable exposure levels based on risk calculations.

A major shortcoming is also that REACH is **mainly based on a substance by substance approach**. **Almost no account is taken of the combined effects of chemicals**. However, the scientific state of art of the branch of toxicology that studies the combined effects of chemicals is sufficiently advanced to assess the risks of these combined effectes as is explained in a report of 2009 from Prof. Andreas Kortenkamp (*School of Pharmacy,* London University) and his colleagues contracted by the European Commission.

There is still **much uncertainty** about how **REACH** will handle **endocrine disrupting substances**. We still have to wait for criteria and tests for endocrine disrupting substances. These are expected at the latest by 14 December 2013. A recently published report ordered by the European Commission, *'State of the Art of the Assessment of Endocrine Disruptors*', also written by Andreas Kortenkamp and his colleagues, indicates the right direction to take: it contains a definition of hormone disruptors, discusses the frameworks for regulatory testing and screening, the scientific results of regulatory relevance (including low dose effects and thresholds, critical windows or life phases of sensitivity, the combined effects of substances, ...), the chemicals of concern and exposure, the European regulatory framework and the proposals by stakeholders and member state authorities. According to Kortenkamp and his colleagues, the EU regulation must identify hormone disruptors by means of a weight-of-evidence-approach. The report emphasises the properties of hormone disruptors, including their potential to cause irreversible and delayed effects. These merit placing them in a separate regulatory category, alongside PBT and CMR substances. Internationally agreed and validated test methods are useful, but only relate to a limited number of endocrine effects. The information and testing requirements determined by the EU regulations do not contain all those measurable effects.

Even though REACH is also applicable to nanomaterials, they don't receive sufficient attention. REACH **does not contain explicit provisions for nanomaterials**. The European Commission did not adopt a recommendation about the definition of nanomaterials before October 2011. According to that definition nanomaterials are substances of which the main constituents have a dimension of between 1 billionth and 100 billionth of a metre (between 1 and 100 nanometres). In order to be considered a nanomaterial, 50% of the particles must be nanosized. The question is whether that definition is not too narrow and whether it will ensure that these materials are adequately assessed. The information about nanomaterials is still incomplete, but there are some indications on the basis of which we could already assert that they should be handled with care.

REACH pays attention to the **chronic toxicity of substances** (certain tests are required from certain production quantities), but not enough yet. ECHA is rather conservative; the acceptability of new methods is still restricted. **Tests studying the critical life phases of exposure** (the unborn child, early childhood and during puberty – vulnerable groups) **and the consequences in the long term are missing and tests studying the low dose effects in the long term are missing as well at the moment**.

From the above we can conclude that REACH **is not taking enough account of the precautionary principle and the principle of physical-chemical hygiene**.

After five years we also have to conclude that the **REACH process is going extremely slowly**. The candidate list of SVHCs only contains 73 substances and the authorisation list contains only 14 substances. The SIN list of ChemSec containing 378 substances demonstrates that it can go faster.

The SIN list – SIN stands for *Substitute it Now* – is based on the REACH criteria for the substances of very high concern. With the list ChemSec and other NGOs want to put pressure on policy makers to speed up the candidate list.

3. Plant protection products and biocides

For a detailed state of affairs of the European, Belgian and Flemish policies with regard to plant protection products and biocides, we refer to the VLK report itself, to the first part of chapter 3.

On a European level we discuss EC Regulation No 1107/2009 concerning the placing of plant protection products on the market, of 21 October 2009, Directive 2009/128/EC for the Sustainable Use of Pesticides, also of 21 October 2009, the harmonization of maximum residue limits through new regulations (No 396/2005 of 23 February 2005 and the amendments via No 839/2008), the 'biopesticides' and finally we discuss the biocides, for which a new regulation is as good as ready.

On a Belgian level we discuss the market authorisation of plant protection products and biocides, the federal Programme for the Reduction of Pesticides and Biocides (PRPB), the National Action Plan (which must be set up in the context of the European Directive (NAPAN) and which will replace the PRPB), and finally the activities of Phytofar vzw, the Belgian association of the plant protection products industry.

On a Flemish level we discuss the policy of the Department of Agriculture and Fishery with regard to plant protection products. We also talk about the 'Decree on the reduction of the use of pesticides by public services in the Flemish region' (or in short, the pesticide reduction decree) of the Flemish government. Finally, we discuss some measurement data with regard to pesticides from the Flemish human biomonitoring programme (and the policy translation thereof) and from the MIRA report of the VMM (Flemish Environmental Agency).

Evaluation of the European, Belgian and Flemish plant protection products and biocide policies

In the European, Belgian and Flemish policies with regard to plant protection products and biocides many steps forward have been taken over the past years. We will summarise the most important achievements in this section.

On a European level a **new regulation** entered into force for **placing plant protection products on the market**. The biggest change is the **implementation of so-called exclusion criteria**: active substances, protective substances or synergists are not approved if they are classified or should be classified as mutagens category 1a or 1b, carcinogenic 1a or 1b, as toxic to reproduction (reprotoxic) 1a or 1b (except for carcinogenic substances and reprotoxic substances for which the exposure of humans in realistic circumstances of use is negligible). Substances with endocrine disrupting properties which are harmful to people are also excluded, unless the exposure of humans is negligible in realistic circumstances of use. Also in this case we have to wait for the criteria of the European Commission. In addition, POPs, PBT and vPvB substances are also excluded.

Just like with REACH **we also see that these regulations shift from a system of risk assessment to a system partly based on hazards and intrinsic substance properties.** The new regulation **confirms an**

existing tendency which has been going on for a number of years. On the other hand we have to **take into account that it will take years before all plant protection products which no longer meet the requirements of the new legislation will have disappeared from the market.**

Even though this new regulation is also based on **an analysis of substance by substance, the regulation does explicitly mention that account has to be taken of the effect of the different substances together.** It is also positive that the **regulation attaches importance to vulnerable groups**, like pregnant women, infants and children. The regulation also **explicitly refers to the precautionary principle**.

Due to the stricter regulation for plant protection products, a **problem** emerges which deserves our undivided attention: due to the extensive testing requirements and the corresponding high costs to put together a file for market authorisation of a plant protection product, several **illegal practices** are emerging. A number of firms are applying strategies to avoid the rules. Therefore, some products are illegally on the market and, on top of that, no adequate risk evaluation was conducted. On the Belgian level a plant protection product committee was set up to tackle this problem in a structured way at government level.

The European Directive for the sustainable use of pesticides goes hand in hand with the new European regulation. The objective is of course excellent, but the question is how most countries will put the directive into practice. **Belgium (and Flanders) is clearly one of the better students in class**, as appears from the state of affairs exposed in chapter 3 of the report. On a federal level a **Programme for the Reduction of Pesticides and Biocides** has existed since 2005. This is now being succeeded by the national action plan or **NAPAN**, which is required by the European Sustainable Use Directive and which must be reviewed at least every five years. The legal competencies for the different sections of the NAPAN are divided between the federal government and regions. **Our country has already progressed quite well on the implementation of the directive**, both on a federal and regional level (Flanders). Not all European member states have come this far. It would be good to have a forum where member states can exchange experiences and good practices. One problem is that it is often very difficult to get information about what member states do.

The new legislation on plant protection products does not contain enough alternative assessment though. There is insufficient public debate about alternative options. Public awareness campaigns can contribute to change the mentality, but that is not enough. A whole series of stimuli has to be embedded in the system, together with information to the public. One of those stimuli is to split up the market authorisation procedure of, on the one hand, products for professional use and, on the other hand, products for non-professional use. In Belgium, this division is almost completed. Also, in Belgium 'biopesticides' (plant protection products made of control agents of biological origin) have received additional support for some years.

Over the past years a **harmonisation of the maximum residue limits (MRL) for plant protection products** has also been issued through regulations. Before that harmonisation all member states applied their own maximum residue levels for plant protection products. MRLs are trade standards and a means to implement good agricultural practices. They are not toxicological or health standards. If plant protection products are used in a correct manner, the MRL should not be exceeded. The MRLs are strictly controlled in Belgium by the Federal Agency for the Safety of the Food Chain.

From the Agriculture Department, Sustainable Agricultural Development division, the Flemish government is stimulating the use of sustainable agricultural production methods. It does so by means of transfer of knowledge at study meetings, by organising demonstration projects whereby sustainable techniques ready to be put to practice are shown and by distributing 'codes of good agricultural practices'. The policy domain Agriculture must contribute to the achievement of the NAPAN as well. The most important task is to implement integrated plant protection management. Flanders is also responsible for the training of users, sellers and informers that is required by the directive.

In Flanders a **pesticide reduction decree** entered into force in 2004. Municipalities could opt for zero use since 1 January 2004 or for a gradual reduction. At the latest on 31 December 2014 all public areas must be managed and maintained free of pesticides. With it one of the requirements of the European Sustainable Use Directive by the National Acton Plan (NAPAN) has been partly met. The directive demands a restriction of the risk or the use of plant protection products in specific areas, such as protected areas and areas used by the public in general or by vulnerable groups like parks, public gardens, sports and recreation sites, school premises and playgrounds, etc. Flanders also has its own **human biomonitoring (HBM) programme** which also monitors the presence of pesticides in the human body. The HBM results are converted into concrete action plans by means of a phased approach. Also in the annual **MIRA report**, which contains a selection of environment indicators with the most current data for the entire environmental domain, we find measurement data in relation to pesticides.

In the very near future the new regulation for biocides will be published which will replace the current directive. Biocides include disinfectants, wood protection products, preservatives for fabrics, leather, rubber ... anti-parasite products (such as insecticides, pest control agents), anti-fouling paint, etc. So, biocides are intended to destroy, deter, eliminate harmful organisms, avoid or control the effects thereof in any other way by using chemical or biological means. The regulation will both apply to the **marketing and use of biocides**. It also applies for **materials and objects treated with biocides**. For biocides as well **exclusion criteria** will apply and again, just as for plant protection products, endocrine disrupting substances will be included in the exclusion criteria. The rules are laid down on the basis of the precautionary principle. A positive evolution is that **new labelling requirements are set out for nanobiocides** and for products treated with biocides and that the regulation also **sets out new rules for a risk assessment of biocides containing nanomaterials**. So, account is taken of the new properties and potential risks of nanomaterials and that is a major step forward compared to other, existing approaches.

The new regulation **does have some major shortcomings** according to environmental organisations; more **exceptions are possible** on the exclusion criteria and there are **no plans to restrict the use of biocides**. One of the biggest problems is that **almost no data on biocides of the member states are available**. The scope of the biocide market is not known and there is currently no requirement to do something about this.

Belgium is one of the European front runners in attention for biocides. The PRPB does not only apply for plant protection products, but also for biocides. Belgium also decided to include biocides in its National Action Plan (NAPAN), alongside plant protection products. Europe is currently only

demanding an action plan for the reduction of plant protection products. It would be a good idea if the whole of Europe would follow the Belgian example.

4. Other legislation, policy measures and policy structures

Chapter 4 of the VLK report provides an overview of other major regulations, strategies and policy measures which play a role in the European, Belgian and Flemish policy with regard to cancer-related chemicals. Some international treaties and conventions play a role as well. Finally, Belgium and Flanders have created some policy structures which must allow for consultation and for an integrated approach.

CLP Regulation

The CLP Regulation (No 1272/2008) which took effect on 20 January 2009 is strongly related to REACH. This regulation is a **new, stricter regulation for the classification, labelling and packaging of substances and mixtures**. Because it will also apply to mixtures, it is also important for plant protection products and biocides. A mixture will now be classified as a harmful mixture when it contains less hazardous substances than before. The CLP Regulation will gradually replace the previous regulation. The old systems and the new system will be used together in the transition period. This period ends on 1 December 2010 for substances and on 1 June 2015 for mixtures. The CLP Regulation is based on the world-wide harmonised system (GHS) of the United Nations for the classification and labelling of chemical substances. The regulation entails new obligations for companies. Since 1 December 2010 they have to classify their chemicals on the basis of the CLP Regulation and the Directive on Hazardous Substances. Since 1 December 2010 all substances that are marketed have to be labelled and packaged according to the CLP criteria. In addition, companies must report both the classification and labelling to ECHA for inclusion in the inventory of classifications and labelling. That is a central database which is created and updated by ECHA and which is also made available to the public in general since February 2012.

In the CLP Regulation hazard categories have to be replaced by hazard classes, which each contain one or more categories. **The new regulation does define more hazards than before. Most of these hazards are health hazards.** The well known hazard symbols with orange background have been replaced by nine pictograms on a white background with a red edge, which are the same across Europe and in a large number of countries around the globe. It is important that there is now a specific pictogram which indicates the following **long-term health risks**: mutagenicity in the reproductive cells, carcinogenicity, toxic for reproduction, target organ toxicity (single exposure/repeated exposure), sensitisation of the airways and aspiration hazard. This means that all CMR substances will now get a clear pictogram, different from the pictogram depicting acute toxicity. Endocrine disrupting properties are still not included in the GHS and therefore not in CLP either.

The CLP Regulation does not only mean a major adjustment for the industry, but also for consumers. It will be quite a challenge to make consumers aware of the new pictograms which will be depicted on the packaging as a result of the new regulation.

Other major treaties, strategies and policy structures at international, European, Belgian and Flemish level

On an international level we are pointing out the importance of the POP Convention and the *Strategic Approach to International Chemicals Management* (SAICM).

On a European level the World Health Organisation Pan-European Process for the Environment and Health is a major process in which a conference of Ministers takes place more or less every five years. This process led to the Environmental Health Action Plan for Europe (EHAPE), to National Environmental Health Action Plans (NEHAPs) and to the Children's Environment and Health Action Plan for Europe (CEHAPE) and national plans in this field (CEHAP). Also the Declaration of Parma, for example, was one of the results. Furthermore, on a European level, there is the Environment Action Programme of the European Community, the Environment and Health Strategy, the Programme of Community Action in the field of public health, the European framework programmes for research and development, the European Partnership for Action Against Cancer and Common Agricultural Policy reform (CAP reform) after 2013.

In our own country some policy structures were set up to allow for consultation and an integrated approach. In a country where legal competencies are so divided, this is not an unnecessary luxury. On a Belgian/federal level there is the National Environmental and Health Action Plan NEHAP, with a turnaround time of five years. There is also a cooperation agreement Environment and Health and a Mixed Interministerial Conference on Environment and Health, representing all ministers with competencies in the area of environment and health. The Conference sets out priorities. We also mention the National Cancer Plan which, in our opinion, does not pay enough attention to the theme of the environment and cancer.

In Flanders the policy with regard to environment and health is part of the Environmental Policy Plan. The Flemish environment and health policy was cast into a network in 2004, the Flemish Medical Environmental Network, which consists of three policy levels. The first level is that of the Medical Environmentalists in Local Health Consultation: they take care of the environmental and health activities at a local level. On the second level we have the Environment and Health Division (Environment, Nature and Energy department) and the Public Health Inspection department (Flemish Care and Health Agency). While the Inspection department has more policy-implementing tasks (inspection), the Environment and Health division takes care of policy-supporting research on the basis of which concrete policy proposals are developed. The third level is occupied by the Environment and Health Centre, a consortium of research groups of all Flemish universities, the Flemish Institute for Technological Research (VITO), the Provincial Institute for Hygiene (PIH) in Antwerp and the Public Psychiatric Hospital Geel. Besides surveillance and human biomonitoring it provides the necessary policy support and also conducts applied environmental and health-economic research.

In this chapter we also focus on the **importance of human biomonitoring (HBM) in environmental and health research**. In combination with other environment and health information the results of HBM help us to verify to what extent the population is exposed to pollutants. HBM is important to estimate the risks of the chemicals on the market. HBM also helps us to determine how efficient new regulations – such as REACH, the new plant protection product regulation and the announced biocide regulation – are to reduce our exposure. Until now only a restricted number of member states have

included HBM in their environment and health policy. Germany is one of the front runners. But **Flanders is also playing a leading role in terms of HBM**. HBM has even been included in Flemish legislation. The Flemish Human Biomonitoring Programme is one of the few HBM programmes which do not only measure exposure markers but also effect markers. In order to translate the results into policy a plan for concrete action and coordinated action (a phase plan) has been developed. Through COPHES – het *Consortium to Perform Human Biomonitoring on a European Scale* – **an HBM pilot project has now also been set up in Europe**. A feasibility study, DEMOCOPHES, will determine whether a coherent approach to HBM is possible in Europe. Belgium and Flanders are also involved in the project and offer their expertise to the other partners.

5. General conclusions

We assume that goverments make sure that we are exposed as little as possible to cancer-related substances in our environment. In the VLK report we investigate whether this is the case, more specifically in the context of the REACH legislation and for plant protection products and biocides.

Based on the state of affairs expounded in the previous chapters, we can conclude that a lot of new regulations have been issued or are in the pipeline since the VLK symposium at the end of November 2005 and that quite some measures have been taken. The attention to the environment and health has significantly increased.

Quite a lot of **steps forward** have indeed been achieved:

- The new regulations include exclusion criteria; this means that substances are excluded because of their intrinsic properties. It is the idea to replace or phase out the substances of highest concern. With this we are slowly shifting from a system purely based on risk assessment to a system which is partly based on the intrinsic hazardous properties of a substance.

- The REACH and CLP legislation make sure that the properties of many more substances will be known.

- Except for substances of very high concern with 'traditional' hazardous properties, such as CMR substances, the regulations and the policies now also pay attention to endocrine disrupting substances. We do have to wait for the final criteria for endocrine disrupting substances, which are expected at the latest in December 2013 from the European Commission.

- People who are handling substances of high concern or objects and products containing such substances, are also better informed, professionals as well as government agencies and consumers.

- More attention is given to vulnerable groups, like pregnant women, elderly people and children, and to the precautionary principle.

- More attention is given to substances or products with a lower risk (such as for example in the plant protection product regulation) and also to sustainable use.

- The government recognises the increasing importance of research and surveillance programmes, like human biomonitoring.

- The government also recognises the importance of an integrated approach, both across policy domains and across national borders. At an international, European and Belgian and Flemish level several consultation structures and options have been set up to allow for this integrated approach.

However, we do see some **shortcomings**:

- The new regulations have been, under pressure of the industry, strongly weakened compared to the original versions. This is certainly the case for REACH. With regard to plant protection products and biocides exceptions are still possible.

- The new regulations are now in place, but it will take a very long time before they will apply in full. The REACH process is burdened by bureaucracy and turns out to be a very sluggish and slowly operating tool. That is why there is currently only a pathetic quantity of substances on the candidate list of substances of very high concern and on the authorisation list. And because of the system in which pesticides are recognised for a period up to ten years it will take years before the new legislation applies to all plant protection products and biocides.

- We have to wait for – hopefully – an adequate definition and criteria for endocrine disrupting substances. The question is whether these will be strict enough to remove a number of major endocrine disrupting substances from our environment (and from our body).

- The new regulations take little or no account of the combined effects of chemicals. The risk assessment is still based on an analysis of separate substances. This approach is too simplistic, leading to the underestimation of the risks of chemicals for our health and for the environment. Nevertheless, adequate scientific methods are available to study the effect.

- The new regulations take little account of the possible effect of low doses in the long term. Principles like adequate control, safety thresholds, acceptable daily doses and 'acceptable risk' are still being applied, also for substances for which there are probably no safety thresholds, like endocrine disrupting substances.

- Even though more attention has been given to vulnerable groups, it is still not enough. There are toxicity tests for reproduction, but on the other hand there is insufficient knowledge about the critical moments of exposure (development of the foetus, the early childhood, pubertal development) and the consequences at a later age. Only few studies go as far as the second generation. Furthermore, an as yet unknown vulnerable group exists of people with genetic features that make them more susceptible to exogenous substances (substances that are foreign to the human body).

- Except in the new regulation for biocides which is about to be issued, the existing legislation has not paid much attention to nanomaterials. In REACH they are regulated because they fall within the definition of chemicals. That is why the general obligations in REACH apply to nanomaterials like for every other substance. But there are no explicit provisions for nanomaterials. Our information about nanoparticles is still very incomplete, but there are a number of warning signals. Nanoparticles are easily absorbed by cells, they easily interfere with DNA. Based on that information we could already conclude that we have to handle them with care. Finally, a definition has been adopted of what nanomaterials are, but the question remains whether it is not too narrow and whether it can ensure

that these materials are adequately assessed and whether they will adequately protect the health of people and the environment against their potential harmful effects. We are waiting for Europe's *'Review of regulatory aspects of nanomaterials'*. Next to that, an '*Analysis of the EU legislation addressing risks from exposure to multiple chemicals from different sources and pathways'* is under preparation as well.

- Modern toxicological tests are not sufficiently included in the new European regulations and much more attention should be paid to the chronic toxicity of substances.

- There is currently not enough harmonisation between the different laws. The way things are now, the legislation for biocides will be more flexible than for plant protection products, even though it often involves the same substances.

- Due to the strict regulations with extensive test requirements and the corresponding high costs, there is a risk of illegal practices being set up. Several firms are active, for example, in the field of evasion strategies, which allows them to get round the strict regulations for plant protection products. Their products are not only illegal on the market; they also escape adequate risk evaluation.

- Not much attention has been paid to the private use of polluting and carcinogenic products. Many substances are obviously forbidden for consumer use. Through the REACH restriction list several substances or other CMR substances are restricted for consumers and cannot be used in mixtures or objects for consumers. But we do still have products in our homes and we do things which may harm ourselves and the environment, such as burning waste in a second-hand barrel which used to contain petroleum. Private use can also be a burden to the environment and to one's health. People do not realise enough that their own use can also make them sick. Professional use is strictly regulated (for example with discharge standards, sanctions, safety data sheets, ...) but there is little or no control on private use. People should be made more aware about the use and also the potential abuse and danger of these products. They have to use their common sense when using these products, always read the label carefully and follow the safety instructions and be especially careful around (small) children.

- Even though all countries must apply or implement the new regulations, there are major differences between the different countries. Not all countries are equally diligent with regard to REACH. The policy on plant protection products and biocides is also very different in different member states.

- A first, modest human biomonitoring project, coordinated in Europe, is currently ongoing, but compared to the United States Europe is lagging behind in terms of HBM. Only a few member states have included human biomonitoring in their environment and health policies. Flanders is one of the European front runners. It is one of the few regions where measuring polluting substances in people is regulated by law. These surveillance programmes are important for the evaluation of new legislation and policy actions which must reduce our exposure to cancer-related chemicals.

In the last chapter of the VLK report we express some general thoughts. To read about these, we refer to the report itself.

6. Policy proposals

Since 2005 major steps ahead have been achieved in the policies on cancer-related chemicals in our environment. The government and policy makers – on an international, European, federal and Flemish level – are becoming more and more aware of the importance of the environment and health and of an integrated approach. Still, this report demonstrates that there is much room for improvement. In the years ahead a number of important opportunities will present themselves. It is important to seize these opportunities for a better physical-chemical hygiene to the greatest possible extent. The following policy proposals formulated by the VLK may be a leitmotiv in this respect.

Specifically for REACH:

1. In the next couple of years **reviews will take place within REACH**. These must be used to the maximum to solve some weaknesses within REACH:

- **Nanoparticles** must be handled separately in the REACH legislation. The evaluation of the scope of REACH in 2012 perhaps provides an opportunity to do this.

- In the evaluation of 2013 of the **endocrine disrupting substances** in REACH the endocrine disrupting substances must be given a kind of cumulative risk assessment. They must not follow the 'adequate control' route in the authorisation procedure. More and more scientific evidence is available which indicates that endocrine disrupting substances have no safety thresholds. Scientific research has also indicated that the combined exposure to endocrine disrupting chemicals can cause additive effects in low doses. So, combined effects can occur as a result of substances at or below safety threshold levels.

- In the evaluation of June 2014 the requirement for a chemical safety report must be expanded to substances meeting the criteria for classification as carcinogens, mutagens or reprotoxic substances (CMR substances) produced or imported in amounts of less than 10 tonnes. In the evaluation of 2019 the chemical safety report must be expanded to all substances for which this requirement does not yet exist.

2. In the context of the information and notification duty within REACH, information must be provided on substances of very high concern if those substances are present in an object in a certain concentration. For the calculation of the threshold value the European Commission must adhere to the definition of an object as defined in the regulation itself. A few member states, including Belgium, are already using this definition. The European Commission currently handles a definition which makes us less aware of substances of very high concern in many objects, i.e. the definition of the object as it is imported or produced. According to the REACH definition, an object is any object which, during the production, acquires a special shape, surface or pattern which largely defines its function rather than its chemical ingredients (e.g. the textile used for car seat lining is an object). If we use that definition we will have the guarantee that we will know of many more objects whether or not they contain substances of very high concern.

3. For CMR substances **the substitution principle must be applied if a suitable alternative exists** for a substance of very high concern, even though the manufacturer claims that the risk can be adequately controlled. Only if no safer alternative is available and the use is essential for society,

authorisation may be granted for the use of a substance. The principle of adequate control is under discussion for quite a number of substances.

4. The success of REACH largely depends on the diligence of the member states, inter alia by preparing annex XV dossiers (for restriction, for including substances on the candidate list of substances of very high concern, for classifying and labelling) or when taking a stand about certain matters. All member states, i.e. including Belgium, must optimally play their role. The process is also going much too slowly at the moment and must be accelerated.

Specifically for plant protection products and biocides

5. The **national action plan for sustainable use of plant protection products** should be **extended to biocides in all member states**, just like in Belgium. Europe must prioritise the reduction of plant protection products and also of biocides and provide more guidance for the implementation of national action plans.

6. The new **biocide regulation** is weaker than the plant protection product regulation. Europe must ensure that the exceptions and the lack of substitution plans do not leave the door open for the continued use of many hazardous biocides. Member states must restrict exceptions to the greatest possible extent. A survey of the use of biocides in the member states and in Europe must be produced as soon as possible.

General:

7. At the latest by 14 December 2013 the European Commission must decide about **a definition and criteria for endocrine disrupting substances**. It is important for the Commission to handle strict criteria which make sure that we will be adequately protected against these substances in the future. In addition, it is important to implement a testing strategy which takes into account the complexity of the endocrine system. Focus must mainly be on identifying chemicals which may affect people's health. The recently published report by Andreas Kortenkamp and his colleagues by order of the Commission, *'State of the Art of the Assessment of Endocrine Disruptors'*, is an especially important guideline to set out adequate criteria and a testing strategy. The EU list of endocrine disruptors must be updated. When the criteria to identify chemicals with endocrine disrupting properties are set out, a classification and labelling system for these chemicals should also be defined.

8. **More attention should be paid to nanoparticles** that flood our society without us knowing all the risks. They must get specific attention in the regulation and specific safety tests are required.

9. When setting out new regulations, **harmonisation** between the regulations is important. One legislation cannot be more tolerant with regard to certain substances than another.

10. We need **European protection standards aimed at the actual living circumstances**, including simultaneous and long-term exposure to several chemicals, some of which may produce a cocktail effect. Those standards must offer protection against prenatal effects during vulnerable phases of foetal development, which could lead to health problems at a later age or even in the next generations. The government must make sure that **vulnerable groups** are taken sufficiently into account: it must make sure that enough tests are conducted up until the second generation of laboratory animals, which look at critical windows of exposure and which study the effects of low

doses. Account must also be taken of the fact that the tolerance of people for exogenous substances is genetically defined.

11. **The risk assessment of combined effects of chemical substances** must be included in the regulation. Adequate scientific methods are already available to study the combined effect. The analysis of separate substances remains important, but is not sufficient. European guidelines are required for the assessment of combined effects of chemicals and more scientific research must be conducted.

12. **Modern toxicological tests** should be used more often to determine the risks and dangers. The regulations must also pay more attention to the **chronic toxicity of substances**.

13. People must be made **more aware of their daily use of chemical and hazardous products and of the possible hazards of such use for their health.** They also have to be told about safer alternatives. It is also important that they are given adequate information about the new labels, with the new pictograms, which are about to be used.

14. Europe must invest even more in **green chemistry**. More research is required about green chemistry and companies must receive more incentives to develop safer chemicals and less harmful products.

15. **Human biomonitoring and monitoring of substances of high concern in our environment** are important tools to measure our exposure to those substances. Human biomonitoring can also show the health effects of the actual exposure of people. Both instruments of monitoring help to determine how efficient policy actions and new regulations are to reduce our exposure. They also show where measures are required and what the policy priorities are in terms of environment and health. Therefore it is very important for Flanders to continue its HBM programme and that Europe as well makes a priority of HBM. An adequately organised and permanent HBM, coordinated by Europe, must be set up. Europe can use the expertise of member states and regions which already have a good HBM, like Germany and Flanders.

16. **Policy makers must aim for a stricter application of the precautionary principle and the principle of physical-chemical hygiene.** Our society must become more alert for early warning signals about whether a substance or product can be harmful and intervene more quickly. Insufficient knowledge may not be an excuse not to intervene. The use must be restricted and a safer alternative must be found. Safer alternatives must always have priority. For optimal cancer prevention, the application of physical-chemical hygiene is indispensable.

17. **Avoiding cancer causing environmental exposure must be an integral part of cancer policy.** This prevention requires a strong cooperation across different sectors and between countries, and also with civil society. The topic of environment and cancer deserves a place in cancer action plans, both on a European and national level. A cancer plan should contain initiatives in the area of primary environmental prevention of cancer.

[1] The full report is in Dutch only.

VLK
Vlaamse Liga
tegen Kanker

Omdat niemand kanker verdient

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