

REACH from the Viewpoint of Environmental Protection

Georg Karlaganis* and Andreas Weber

Abstract: In 2005, Switzerland harmonised its law on chemicals with the related EU law on chemicals by bringing the Chemicals Act and the PARCHEM ordinances into force. Unless this law on chemicals is revised again, both at act and at ordinance level, Swiss regulations will again differ from those of the EU in important respects. The question therefore arises of whether and to what extent the Swiss legislation on chemicals should be adapted to REACH. In this article, we consider the need for REACH in order to resolve the existing chemicals issue, the contribution of the new regulations to the protection of the environment, the relationship between the new EU regulation and the existing Swiss legislation and how the possibility of collaboration with the European Chemicals Agency could influence the Swiss adaptation process.

Keywords: Articles · Chemicals legislation · Cosmetics · Downstream users · Existing chemicals program · Formal agreement with the EU · Implementation · Involvement of third parties · Notification · PBTs persistent bioaccumulative toxic chemicals · REACH

1. Have Existing Substances Programmes Failed?

Many chemical substances came onto the market at a time when there were no testing requirements and hardly any standardised evaluation methods. To this day, many of these substances are still inadequately tested and assessed. This is without doubt an unacceptable state of affairs, and one which should be rectified. This is one of the main arguments employed by the EU Commission to justify the necessity of the new REACH regulation.

This motivation gives the impression that the current EU regulation on existing substances [1] and the EU existing substances programmes that it spawned have failed. We can agree with this conclusion only to certain extent. It is undoubtedly the case that under the current existing substances regulations the reprocessing of existing substances has progressed more slowly than planned. The same applies to the voluntary existing chemicals programme run by the Organisation for Economic Cooperation and Development (OECD), in which representatives of the chemicals industry and the authorities in industrialised countries manage the processing of substances that are manufactured or imported in annual quantities exceeding 1000 tonnes. Nevertheless, the EU existing substances directive has also achieved major successes. The risk of several widely used substances, whose risk potential has been publicly debated for years, was evaluated on the basis of the current EU existing substances regulations in a complex procedure that ended with a recommendation being made by the Commission on a risk limitation strategy. An example is the nonylphenol ethoxylates, which due their surface-active properties, have been used in a wide variety of products such as detergents, cosmetics, metal and leather processing products or even in plant protection products. Another example is the brominated flame retardants pentabromodiphenyl ether and octabromodiphenyl

ether, which are widely used in vehicle upholstery, in polyurethane foams or in electrical and electronic equipment. The risk limitation strategies for these substances have led in the EU to the enactment of far-reaching prohibitory regulations. Switzerland adopted these prohibitions in 2005 in the Ordinance on Risk Reduction Related to Chemical Products. In the case of nonylphenol ethoxylates, Swiss efforts to impose a ban had previously failed due to resistance from the business community. Switzerland has therefore ultimately benefited from the results of the EU existing substances programmes.

Regulations Are only as Good as Their Implementation

It is not our intention in using these examples to create the impression that all the existing substances issues would have been resolved equally well under the existing law. *What is needed is for the work to be speeded up.* However, it cannot be presumed that the legal rules alone would inevitably and automatically lead to the elimination of the pollutants. The decision to prohibit a substance or to refuse to authorise it under a REACH procedure will require extensive preliminary work not only by industrial companies, but also on the part of the authority involved. The question of whether REACH will be a success will therefore depend on the human resources that governments are prepared to provide in order to implement REACH.

*Correspondence: Prof. Dr. G. Karlaganis
Federal Office for the Environment FOEN
Substances, Soil and
Biotechnology Division
CH-3003 Bern
Tel. +41 31 322 69 55
Fax +41 31 324 79 78
E-Mail: georg.karlaganis@bafu.admin.ch
www.environment-schweiz.ch

2. Strengths of REACH

REACH is more than simply an obligation to test substances based on a threshold production volume and to report back to the authority concerned. REACH introduces many essential new elements. One of these important elements is that the responsibility concerning evaluation is imposed on industry. In the current system EC authorities are responsible for undertaking risk assessments of substances. The change of allocation of responsibilities will hopefully contribute to awareness.

We would also like to further discuss three issues that directly improve environmental protection: these are the provisions on downstream users, the broadening of the scope of the regulations on chemicals to include articles, and the intention to give special priority to substances whose profile is indicative of persistence, bioaccumulation, and toxicity (PBT).

The Role of Downstream Users

Exposure and effect determine the risk of a substance. Effects can be determined by toxicological and ecotoxicological tests. The same applies to the chemical properties that influence its dispersion and degradability in the environment. Nevertheless, it is not the properties of the substance alone that influence environmental exposure. An essential additional element is the way in which the substance is used and the products in which it is used. It goes without saying that the manufacturer of a substance has a more or less clear idea of the purpose that the substance should or can have. Often though, substances, due to their properties, are suitable for purposes that differ from those that the manufacturer had originally conceived. Ultimately, it is more often the person who devises a product and not the manufacturer of the substance who decides on its purpose and thus the way in which the chemicals enter the environment. The manufacturer of a product is normally better informed as to the details, such as the required level of a substance in the product, its dosage or its method of use. It is therefore self-evident that downstream users must be made subject to the requirement to evaluate the risks.

Downstream Users in Switzerland Already Have Obligations

Not without some pride can we point out that in Switzerland the importance of the role of downstream users has long been recognised. On 7 October 1983, the United Federal Assembly passed the Environmental Protection Act [2]. The concept of self supervision was enshrined in the chapter on environmentally hazardous substances. In 1986 in the Ordinance on Environmentally Hazardous Substances

[3], the Federal Council introduced more detailed requirements in relation to self supervision. In accordance with these provisions, every manufacturer of chemicals or products containing chemicals – whether they are substances, products or even articles – must assess their environmental risks as part of the self supervision process. In order that environmentally acceptable use by downstream users and end users is ensured, manufacturers are also required to inform customers about the environment-related properties of their products and to make sure that, if the product is used in accordance with the instructions, no danger will result. Accordingly, downstream users in Switzerland have been subject to this duty for a long time. Although the Substances Ordinance has been repealed in the intervening period and was replaced on 18 May 2005 by various other ordinances, the concept of self supervision and its application to downstream users have been retained. Today, we find the relevant provisions in the Chemicals Ordinance [4]. Its scope of application has in the meantime been extended to cover health protection. However, the formal requirements have not been specified in such specific terms. For example, there is no requirement to draw up a report. Proving that a manufacturer has fulfilled his obligations in their entirety and that all essential uses of a substance have been assessed is therefore not a simple matter in Switzerland today.

REACH and Articles

According to the draft REACH Ordinance all substances in articles – even those not classified as dangerous – must be registered if the substance is intended to be released under normal or reasonably foreseeable conditions of use. If the substance present in an article meets CMR- or PTB-criteria and if it is present above a concentration of 0.1%, a notification is needed, unless the producer or importer can exclude any exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. Under certain conditions, the agency can request a registration for any substance contained in articles.

From the standpoint of environmental protection, articles that contain or have been treated with chemicals are often regarded as a kind of storage depot. Often pollutants remain enclosed in an article while it is being used and are seldom if ever released. This does, however, not mean that entry into the environment remains forever impossible. A change in conditions can trigger or accelerate the release process. For example, pre-fabricated metallic elements that are treated with anti-corrosion agents containing lead and are used in bridge building, pylons for carrying overhead high-voltage electric ca-

bles or large tanks become a source of entry for lead into the soil and into watercourses when they are repaired and their elements have to be sanded down. When waste is disposed of or recycled, pollutants can also be released from articles. This can clearly be seen when waste is stored in landfills. To avoid such releases, in Switzerland all combustible waste that is not recycled must be incinerated in appropriate plants. In landfills for inert materials, only rock-like wastes may be disposed of from which virtually no pollutants will be leached out by rainwater. These include materials such as construction waste (concrete, bricks, glass, road rubble). Materials that may be disposed of in so-called residual-waste landfills should generally yield a leachate that can be discharged to receiving waters without first being treated. Residual-waste landfills are designed for the disposal of materials of known composition, with high concentrations of metals and only a small organic component, and which cannot release either gases or substances readily soluble in water. These sites are subject to more stringent requirements than landfills for inert materials. Impermeable linings are required for the base and sides of the landfill, and leachate is to be collected and, if necessary, treated. But even if all these very strict requirements are met, the release of pollutants that are for example used as additives may never be excluded totally. Finally, pollutants in persistent goods can make disposal in incineration installations harder or more expensive and make recycling difficult or even impossible and thus indirectly have an adverse effect on the environment.

It is therefore an obvious and consistent move to make articles subject to an evaluation obligation as well. It is certainly unwise, though, to have high expectations of the evaluation obligation. Rarely does any specific article generate on its own a pollution level that is clearly unacceptable according to scientific evidence. In most cases a variety of products from different manufacturers together make a contribution to the overall level of pollution. It is unlikely that businesses will consistently avoid the use of pollutants in products in future as a result of the evaluation obligation. Regulation will however contribute to an increase in awareness and thus sensitise manufacturers to environmental protection. In certain cases, this will undoubtedly lead them to replace one substance with another that gives less cause for concern, especially if there is a choice of suitable substances available.

Environmental Requirements for Articles Already Exist in Switzerland

In Switzerland, the Environmental Protection Act and the Substances Ordinance included articles under the evaluation ob-

ligation as part of the self supervision process. Unfortunately, it has not been possible to introduce a corresponding provision in the new Chemicals Act of 2000 to meet concerns about health protection. The Chemicals Ordinance [4], which now comprehensively regulates the requirements of self supervision based on both the Chemicals Act and the Environmental Protection Act, therefore, differentiates between evaluation procedures for articles with respect to human health and environmental impacts; it only imposes an obligation in relation to environmental protection aspects. In the case of articles containing dangerous substances (dangerous constituents), manufacturers are required to ascertain whether the dangerous constituents can endanger the environment or indirectly endanger people when these articles are used as intended, or in a foreseeable manner, and when they are disposed of in accordance with the relevant rules.

It is pleasing to note that the EU is now heading in the direction that Swiss legislators have taken in environment law.

Authorisation for PBT Substances

In the past in the EU and in the OECD it was all too often the case that production volumes were decisive in determining whether an existing substance would be evaluated by an authority. Without doubt, larger production volumes bring a corresponding increase in the probability of environmental exposure, in theory at least. However, persistence and an accumulation tendency increase the exposure potential in equal measure. It must therefore be welcomed from the point of view of environmental protection that these inherent substance properties are also taken into account when fixing priorities, and that substances with a profile of this kind are given special attention. If we look at the list of substances that are prohibited or drastically restricted in their use at a national or international level (a list that has increased considerably in length over the years), it can be seen that it includes a large number of substances that possess the PBT profile of the prospective REACH regulation. In our opinion, therefore, the intention of making such substances subject to authorisation is the correct approach. Naturally, any refusal of authorisation, or indeed prohibition, must in every case be preceded by a risk evaluation and decisions must not be taken simply on the basis of the inherent properties of a substance. Account is taken of this, however, in the REACH regulation.

3. Does REACH Have Weaknesses as Well?

It goes without saying that all regulations have their weak points. This even applies to Swiss regulations! When voicing

criticism it is important to adopt a cautious approach. Nevertheless, we would like to draw attention to one point in relation to REACH where we think a better solution could have been found.

The Interface Issue

Our concern relates to the interfaces with other European regulations on chemicals in the broadest sense. In justifying the necessity for REACH, the EU authorities adopted a self-critical approach and described the existing law on chemicals as a patchwork that had grown over many years. With a certain pride, it was announced at the start of the consultative committee stage that REACH would result in 40 existing directives being repealed. This sounded tantamount to a complete revision of the law on chemicals. However, also included in this total were the amendment directives. If these are disregarded and only the basic legislation considered, then REACH essentially effects only the Directive on Dangerous Substances [5], the Directive on Dangerous Preparations [6], the Directive on Existing Substances [1], the Safety data Sheet Directive [7] and the Directive on Restrictions on Certain Substances and Preparations [8]. Numerous other directives and regulations relating to specific products remain in existence. This is an understandable and probably also a pragmatic approach. Provided the scope of the relevant legislation is clearly defined and the demarcation lines between these enactments are drawn, no legal loopholes or duplication will result. An example of this are the prohibitory regulations: limitations and bans for one and the same substance may in future be found at the same time both in REACH and in other directives, such as in the directives on end-of-life vehicles [9], electrical and electronic equipment [10], batteries [11], packaging [12] or substances that deplete the ozone layer [13][14]. As manufacturers working in the each field primarily take account of the specific legislation, this solution may even prove to be the best means of reaching those whom the legislation addresses. Manufacturers must however take note that certain bans in REACH are total bans that may also affect their specialist field.

In the case of cosmetics, however, the future legal requirements are, in our view, far from comprehensible and excessively complex. Basically, the Cosmetics Directive [15] continues to apply. Its aim, however, is simply the protection of health and it imposes no requirements with regard to testing or the evaluation of environmental behaviour of chemicals used in cosmetics or the cosmetics as such. Accordingly, no classification or labelling in respect of any environmental hazard posed by cosmetics

is required. From the environmental protection standpoint, it would be better if REACH closed these loopholes. To some extent REACH does in fact seem to bring about certain improvements here. Substances used in cosmetics that are manufactured or imported in quantities of one tonne or more per annum are subject to the registration requirement. Conducting tests in relation to their environmental properties (degradability, toxicity to fish, etc.) and producing a substance safety report are however only required when the quantities exceed ten tonnes per annum. PBT substances would therefore be subject to authorisation. This should ensure that regional problems, such as the accumulation of cosmetic constituent substances in the marine environment, can be prevented. Nevertheless, it does seem that cosmetics have again escaped being made subject to specific environmental requirements. This means, in theory at least, that it should be possible to continue to use surfactants in products like shampoos or shower gels without any requirements being imposed as to their degradability. If the production or import volume per annum does not exceed 10 tonnes, these do not even have to be tested. This is hard to understand, all the more so because for all surfactants in washing products and detergents mineralization has to be proven experimentally according to the new provisions of the Detergents Regulation. By the way: the existing Swiss requirements for cosmetics are not stricter.

4. Will Switzerland Adapt its Law on Chemicals to REACH? Studies of Different Scenarios

Differences in Chemicals Regulations between EU and Switzerland Will Arise

In 2005, Switzerland harmonised its law on chemicals with the EU law on chemicals by bringing the Chemicals Act and the PARCHEM ordinances into force. Without the further revision of its law on chemicals at both act and ordinance level, Swiss regulations will once again differ from those of the EU in important respects. The question therefore arises of whether and to what extent the Swiss law on chemicals should be adapted to REACH.

Study of Different Scenarios

Whether Switzerland adapts its legislation to REACH is a political decision. The federal administration has the task of presenting the pros and cons of the various scenarios and preparing for a decision to be taken. Here the starting point is the two extreme scenarios: Scenario 1, 'no adoption' and Scenario 2, 'complete adoption'. In the

case of 'no adoption' two sub-variants may be considered: 1A 'no adoption, *status quo* with PARCHEM' and 1B 'no adoption, lowering the environmental health and safety standards'. In the case of 'adoption', three sub-variants may be considered: 2A 'no chemicals agreement with the EU', 2B 'mutual recognition agreement (MRA) in relation to products', and 2C 'integration agreement with the EU with participation in the new European Chemicals Agency' in Helsinki, which should come into operation in 2008.

Scenario 1A 'no adoption, *status quo* with PARCHEM': REACH lessens the requirements for new substances put on the market in low quantities. If Switzerland does not adapt its legislation, companies operating on a Europe-wide basis will not benefit from such liberalization. For existing substances, the stricter requirements of the REACH Regulation would have to be fulfilled, and for new substances the stricter requirements under Swiss law. We therefore expect that industry itself will be interested in at least some adaptation of the Swiss legislation. Scenario 1A therefore seems to be unlikely on the long range.

Scenario 1B 'no adoption, lowering the environmental health and safety standards': This hypothetical scenario describes an 'offshore situation' with production areas in Switzerland designed for substances to be exported to non EU countries. For these substances EU registration could be avoided. Non-registered chemicals could for example be exported to Asia or America according to their national legislation. The authors of this paper as co-workers of the Federal Office for the Environment will obviously not defend scenario 1B. According to the view of the authors it is neither in the tradition nor in the interest of the Swiss chemical industry to walk along this avenue. The idea of a Swiss island in the centre of Europe with lower environmental health and safety standards than the other 30 European countries (including European Economic Area (EEA) countries Norway, Island and Liechtenstein) would damage the global reputation of Swiss chemical industry.

Scenario 2A 'adoption, no chemicals agreement with the EU': This scenario would mean that Switzerland in a parallel process to the EU would duplicate the whole registration and evaluation work. In the view of the authors of this article, a duplication of the procedure for the registration and authorisation of substances in Switzerland in parallel with the EU would neither be expedient nor could it be implemented without having to employ an unreasonable high number of staff. Scenario 2A would therefore be very expensive and not cost effective.

Scenario 2B 'mutual recognition agreement (MRA) in relation to products': The idea of a chemicals MRA goes back to 1993 to the negotiations of the bilateral agreement I. At this time Switzerland envisaged the collaboration with the EC similar to that between the EC and the EFTA countries Norway, Island and Liechtenstein as defined in the EEA treaty. New substances manufactured in one of the Contracting Parties have to be notified only to the responsible authority in the country where the new substance is manufactured. Substances imported from outside the Contracting Parties have to be notified to the responsible authority of the Contracting Party where the first import is intended to take place. The procedure ensures that the same chemical has to be notified only once and that chemical products containing it can circulate in the whole European Economic Area. EEA countries take also part in the expert group meetings of the EU. The collaboration between Switzerland and the EU in this scenario has to be negotiated with the European Commission. Exploratory talks with representatives of the federal administration started in March 2006. In scenario 2B Switzerland would need the same status as Norway in relation to information access (access to confidential chemical notification dossiers, participation in the working groups as an observer). Without information access scenario 2B would be a 'black box'.

Scenario 2C 'integration agreement with the EU with participation in the new European Chemicals Agency': As a result, if it is to adapt to REACH, Switzerland should be able to participate directly in the EU implementation of REACH. This would mean that Switzerland would have to participate fully in the bodies set up to implement REACH at Community level – such as the Member States Committee, Risk Assessment Committee and Socio-economic Assessment Committee – and in the processes (e.g. substance evaluation, preparation of substance dossiers for authorisation or for restrictions). In view of the substantial amount of work that is expected the authorities will have to do in relation to the registration and evaluation of chemicals, the EU is aiming to share the burden efficiently among member states and seems interested in non-member states also playing a part in the REACH process. At any rate, Article 117 of the REACH draft in its revised version after the first reading provides for the possibility of the involvement of third countries. This would however be dependent on a formal agreement being reached with the third parties concerned. The implementation of Article 117 is a challenge for all interested non EU countries. For the time being it remains open which country from which continent will be the first to participate under Article 117.

5. Conclusion

Conclusions Have Yet To Be Reached

In Switzerland, no conclusions have yet been reached about REACH. There are various reasons for this. On one hand, the debate on the REACH regulations is still ongoing in the EU, with the second reading taking place in the EU Parliament in 2006. In addition, in view of the complexity of the legislative proposals, it is not easy to assess what the effects of adopting REACH would be. Both chemical industry and federal administration have been studying the consequences of REACH since the beginning of 2006. However, it will take some time to finish these assessments if they should answer the specific questions outlined in this paper with an environmental health and safety as well as with an economic approach.

No Agreement with the EU in the Chemicals Sector

At present, there is no such agreement between Switzerland and the EU in relation to the chemicals sector. As stated in the response to a parliamentary interpellation from the Swiss parliamentarian Simonetta Sommaruga [16], the Federal Council has for a long time been striving to cooperate with the EU in the implementation of the legislation on chemicals, quite apart from its interest in the current developments. During the talks in 1993 on the first round of bilateral agreements, it was planned to include provisions relating to chemicals control in the Mutual Recognition Agreement (MRA) between the EU and Switzerland. In the course of the negotiations, it was concluded that the pre-condition for the inclusion of this product chapter in the Agreement – the equivalence of the respective legislation of the parties on the matter – could not be met at the time. The Federal Council has stated that when the Swiss law on chemicals is equivalent to the EU law, an examination should be made of the extent to which a broadening of the scope of the MRA to include aspects of chemicals control would be possible as part of the ongoing efforts to update the MRA, in order that account may be taken of previous concerns. At present, Switzerland and the EU have equivalent legislation.

Federal Working Group Study of Adaptation to REACH

The Federal Council has stated its position in its responses to the parliamentary interventions raised so far [16][17]. It is of the view that the drafts of REACH contain essential new elements that would lead to an improvement of the protection afforded to human beings and the environment. Basically, the Federal Council is pursuing the objective of adapting Swiss law to the new

EU law in such a way that the level of protection is maintained or increased and trade barriers are avoided wherever possible. In the report on the programme of legislation for 2003–2007 [18], under Objective 2 (ensuring a sustainable environment), the parallel introduction of REACH in Switzerland was endorsed and a discussion paper on the harmonisation of the Swiss law on chemicals with the new EU law on chemicals was announced as a priority for the legislative programme. A working group from the Federal Office for the Environment, the Federal Office of Public Health and the State Secretariat for Economic Affairs has begun work on a report to set out the effects of harmonising Swiss law with the REACH regulations. This report will contain information about the assessment of different scenarios relating to environmental health and safety as well as economical consequences.

View of the Authors

We think that REACH will be an added value to environmental protection also for Switzerland. Therefore we are in favour of an adaptation of the Swiss legislation to REACH. For efficiency reasons burden sharing is important. As a consequence we prefer scenario 2C 'integration agreement with the EU with participation in the new European Chemicals Agency' as our favourite option. It would allow a true collaboration between Switzerland and the EU in the implementation process of REACH. It would also bring Switzerland into a similar position that Norway has been in since 1993 as an EEA contracting party.

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