Paris, 24th June 2020

MEMO FROM FRENCH AUTHORITIES

"This is a courtesy translation and in the event there are any differences between the French and English texts the French text governs"

"Ceci est une traduction de courtoisie. Au cas où apparaîtraient des différences entre les textes en langues française et anglaise, la version française prévaut"

Subject: Contribution from the French authorities on the consultation of the roadmap published by the European Commission on the "Sustainable Chemicals Strategy (for a European Union environment free of toxic substances)".

The French authorities thank the Commission for the consultation on the roadmap for the future EU chemicals strategy. They welcome this review and this presentation of the European Union's thoughts and courses of action.

In addition to their response to the public consultation, the French authorities would like to comment on the following points.

1. Adapting the regulatory framework on chemicals to better protect citizens

1.1. Basing of the regulatory framework on the application of the precautionary principle

The scientific discoveries of the last 30 years on the specificity of action of hazardous substances, the existence of "cocktail effects", the questioning of classic (or monotonic) dose/response relationships, the possibility of effects delayed in time or even transgenerational and the importance of chronic effects have called into question the relevance of the toxicological models used and the general approach to risk management through the "toxicological reference value", the "acceptable daily intake", the "tolerable daily intake", etc. According to the French authorities, the Council and the European Parliament, these scientific data reinforce the need to apply the precautionary principle, a principle enshrined in the FTEU. The application of this principle should make it possible to reduce exposure and thus better protect the population and the environment from the hazard linked to exposure to these substances.

The French authorities wish to emphasise that the impossibility of attributing responsibility to a particular substance or factor, in particular in the context of epidemiological studies, must not be used to justify the absence of political decision-making to protect citizens and the environment. This calls into question the principle of prevention and precaution, which is not acceptable.

The French authorities would like the Commission to examine the regulatory framework on chemicals and ensure that all the regulations concerned include provisions enabling the precautionary principle to be applied effectively. The example of E171 has shown that this is not the case. The French authorities note that the level of proof required to justify a danger is too high, and that it is often up to the public authorities to prove a level of risk with certainty. They emphasise that in cases of uncertainty about the hazards of a substance, or in the absence of reliable data from economic actors, the precautionary principle must be applied and the procedures adapted in the regulations. The recent example of ECHA's Member State Committee decision on Resorcinol shows that the same applies to hazard identification.

1.2. Hazard identification of chemicals

A. Hazard identification

The French authorities point out that the identification of the hazards of a substance, or a group of substances, i.e. the characterisation of its intrinsic properties, is the first step towards adequate risk management and should not depend on sectoral regulations or exposure. For example, it is not understandable that the substance acetamiprid is recognised as very persistent under the Biocide products Regulation but not under the Plant Protection Products Regulation.

The French authorities consider that in order to ensure that the hazard identification of a substance is consistent with all other identifications, it would be appropriate to separate the hazard identification of a substance (or group of substances) from its approval according to its use. The French authorities consider that this work should thus be entrusted to a single body at the European level and recommend that ECHA should be responsible for it and have the means to do so.

The French authorities underline that the CLP Regulation is the appropriate tool to act on the hazards of substances, based on self-classification by companies, and allowing in some cases a minimum harmonisation of hazards, based on harmonised identification criteria.

The French authorities express the importance of making this classification process complete for certain categories of hazards (hazards imperfectly or not covered by CLP at this stage: EP, persistence,

bioaccumulation in particular) first at the European level before taking these principles to the international level, and to have an ambitious program of harmonized classifications (without calling into question the primary responsibility of manufacturers placing products on the market) so that the risks are then managed in an adapted manner in the various sectoral regulations (in priority for the properties of very worrying hazards which can lead to automatic management on the basis of harmonized classifications): e.g. prohibition of active substances and co-formulants in pesticides, prohibition of carcinogens in cosmetics, in textiles, proposed ban on skin sensitizers in textiles, proposed ban on certain substances in tattoo inks, etc.). This programme will have to be based on good cooperation between the Member States by ensuring sufficient allocation of resources at European and national level. It seems necessary for ECHA, at the request of the Commission, to be able to submit dossiers for harmonised classification. This also raises the question of the ever increasing responsibilities of the RAC. Its size should be commensurate with these responsibilities and ensure that expertise is provided collectively (e.g. ensure that each dossier is seen by a sufficient number of members).

As such, the French authorities indicate that a review of the division of responsibilities is necessary to ensure good readability and effectiveness, in particular who initiates the various procedures (classification, restriction, occupational exposure limit value, etc.). The risk management procedures already included in the existing regulations and directives will have to be reconsidered in the light of the new procedures laid down for the identification of hazards.

B. Tests and data required for hazard identification

The French authorities also point out that data requirements (tests required, independent studies to be taken into account...) are sometimes insufficient in European regulations to enable the identification of hazardous substances (particularly endocrine disruptors) regardless of the sector, including in the regulations on pesticides and chemicals (REACH).

The Commission should ensure that data requirements are completed in a harmonised way across the whole of EU legislation and, where appropriate, made mandatory in a horizontal regulation such as REACH or CLP.

The French authorities recall that the burden of proof rests on industry, which must also take into account all the data available in the scientific literature. This is why the data requirements to be provided must be as exhaustive as possible insofar as these data can reasonably be required from companies, in order to enable the identification of hazards based on the elements provided by industry.

At a minimum, the French authorities request the systematic inclusion of in vitro tests in the annexes of the REACH regulation to allow the acquisition of data on the hazard of substances in the registration dossiers, in particular to identify endocrine disrupting properties. Thus, in the case of endocrine disruptors (EDs), if this "screening" shows an endocrine disrupting effect, more complete tests, comparable to those required under the regulations on plant protection and biocidal products, would then be required to identify the EDs that are known, presumed or suspected.

Where appropriate, the development of more effective (rapid, reliable) and affordable (including for SMEs) tests should be promoted.

C. Substances of very high concern (SVHC)

The French authorities point out that the inclusion of a substance on the SVHC list has two consequences: the possibility of inclusion in Annex XIV and therefore management by authorisation, and the obligation to inform the consumer and improve traceability throughout the value chain. For the time being, this inclusion is also the only way to identify in a harmonised manner at European level certain hazards not otherwise

foreseen (endocrine disruption, etc.). On the objective of consumer information, the French authorities inform the European Commission that two provisions on information on dangerous substances are provided for in the anti-waste law for a circular economy, voted in February 2020 by the French parliament.

Article 57 f of the REACH regulation provides for an "equivalent level of concern" (ELOC) criterion. This criterion has the merit of being able to recognize hazard properties other than CMR, PBT, vPvB but also introduces a lot of ambiguity, and is a source of litigation contrary to the initial objectives of the regulation and mobilizing many public resources (for example the litigation on the identification of Bisphenol A as an endocrine disruptor and the recent decision of the Committee of Member States of ECHA on Resorcinol). Therefore, the French authorities ask the European Commission, as soon as possible, to explicitly mention the hazards rather than using the ELOC criterion.

The French authorities recall that they would like Article 68(2) of the REACH Regulation to apply also to substances presenting one of the most serious hazards mentioned above (and not only to CMR substances as is the case today).

1.3. Risk management of hazardous chemicals

A. Implementing the "essential use" approach

The French authorities are asking to include the "essential use" approach, to decide on the ban and phase-out of the most dangerous chemicals.

This approach could be broken down into three levels of decreasing requirements:

1- Non-essential uses for health, safety or the functioning of society;
2- Uses that fulfil important functions but for which there are alternatives that are equally effective, safer and available from a technical and economic point of view;
3- Uses considered essential because they are necessary for the health, safety or functioning of society or because alternatives are not yet available.

B. Risk management and the prohibition principle for the most dangerous substances, in particular for exposures of the general public

The French authorities, in view of the danger of certain chemical substances, the methodological and scientific limitations in identifying safe thresholds for exposure to these substances, and the failure to take account of cocktail and transgenerational effects in setting exposure thresholds, ask the Commission to provide for the prohibition in principle of substances meeting the criteria of substances of very high concern in all sectors exposing the general public or the environment (cosmetics, toys, MCDA, etc.).

This principle of banning the most dangerous substances should provide for the possibility of derogations or exemptions. It could be adapted according to the level of evidence, the level of exposure and risk to the population and the environment during the use of the substance (alone, in a mixture or in an article) as well as on the basis of essential uses, which are to be defined at European level.

The French authorities point out that this approach is already implemented in the regulations on substances that deplete the ozone layer and on pesticides, for example. Indeed, in view of their danger and the existence of alternatives, certain substances in these regulations are banned.

C. Development of the group of substances approach

The French authorities recall that they are in favour of the recommendation established by the Commission during the discussions on the revision of the REACH regulation: the systematisation of the approach by groups of substances with similar chemical structures, rather than by individual substances.

The French authorities support this approach, the aim of which is to improve the consistency of evaluations between substances in the same group and the efficiency of the work of the evaluation agencies. This approach by group of substances is essential for better management of dangerous substances: it makes it possible to act more quickly and to limit animal testing through the use of in vitro and in silico tests. The French authorities consider that this approach must be fully implemented as soon as possible in order to protect the population and the environment and avoid regrettable substitutions (as has happened with bisphenols and phthalates).

The French authorities welcome the implementation since 2019 by ECHA and the national agencies of this approach, which should be generalised to all agencies.

Together with the Member States, ECHA has examined around 220 substances registered at more than 100 tonnes per year and allocated them to different groups in the "chemical universe" for coordinated regulatory action. For 56% of these substances, additional data were required to clarify the need for further risk management. For 22% of the substances, no further action was proposed and 7% were identified as high priority for EU regulatory risk management.

Therefore, the French authorities support the implementation of the following recommendations:

- Optimise the selection of groups of substances, the generation of data for these groups of substances and their evaluation to ensure that substances move as quickly as possible from evaluation to regulatory risk management;
- Further strengthen cooperation and coordination between authorities.

However, this approach should not be to the detriment of industry's obligation to provide data on their registered substances. This approach could therefore be applied preferentially to propose management measures rather than to dispense with tests.

D. Taking into account the cocktail effect

The French authorities point out that they provided an official position on the subject when the General Food Law was revised. In particular, they point out that taking proper account of "cocktail effects" is one of the main priorities that the European Union has set itself (for example, in the 7th Environment Action Programme, reiterated at Council level by its conclusions of December 2016).

Generally speaking, inter-agency coordination is necessary at a cross-cutting level to take account of all the exposures to chemical substances to which the population and the environment may be exposed.

The French authorities underline the need to address chemical cocktails by ensuring that adequate risk assessment provisions and methods are included and applied in all relevant legislation, by strengthening risk assessment methods and practices for chemical cocktails, and by establishing a coordination mechanism to deal with chemical cocktails subject to different pieces of legislation.

The French authorities request the organisation of a discussion dedicated to the issue of cocktail effects of chemicals. These discussions could address :

- The methodological work in progress (in particular the EFSA guide on mixtures but also the work of ANSES and INSERM in France) ;
- The need to reflect on how to integrate the consideration of the cocktail effect in a cross-cutting manner in European regulations on chemical substances;
- The assessment of existing regulatory tools to protect human health and the environment from the cocktail effect and in particular from additive effects, in order to better mobilise these tools in the future, in particular in relation to food regulations;
- Organising the production of scientific data: mapping the properties of single substances in order to better anticipate the effects of mixtures, grouping substances by reactive families (likely to cause effects through additivity), reinforcing bio-monitoring studies on a European scale of both populations and the environment, identifying the most frequent co-exposure profiles at European level, etc.

The French authorities consider that during the risk assessment work, it is particularly important for experts to highlight the limits and clearly express the shortcomings related in particular to cocktail effects. These elements are crucial in a context where it will be impossible to study all the possible combinations of chemical substances and to give tools to the risk manager so that he can apply the precautionary principle when necessary. Also, they recall that risk management must be based, inter alia, on the application of the precautionary principle and the implementation of the non-essential-use approach.

1.4. Providing a regulatory and economic framework conducive to the substitution, competitiveness and development of virtuous enterprises

Substitution of hazardous products, whether substances or manufacturing processes, can be a competitive advantage for the European Union.

The French authorities call on the European Commission to integrate into the European strategy tools to help foster innovation and research by enterprises in this field, the dissemination of good practice in functional substitution and networking, and the consolidation of know-how.

The French authorities note that companies at the forefront of ambitious chemicals management often face competitiveness difficulties in the face of a regulatory framework that provides little incentive. The French authorities consider that the EU strategy on chemicals must support, including through financial instruments (mobilisation of the EFSI, support for R&D&I via Horizon Europe), those companies that invest in more sober and safer means of production.

The French authorities call on the European Commission to send clear signals to industry to step up its efforts to phase out the most dangerous substances and thus achieve the "zero pollution" objective.

In this respect, synergies should be established between the various European regulatory frameworks dealing with chemicals on the one hand and the operation of the industrial plants that use and/or produce them on the other. As mentioned by the French authorities in the context of the evaluation of the IED (Industrial Emissions Directive), in terms of substance, the potential of the Best Available Techniques Reference Documents (BREFs) and operating permits should be better exploited to meet the European

objectives set out in various regulatory frameworks (including that relating to chemicals) and the ambitions of the Green Deal. The inclusion of emerging issues (endocrine disrupters, nanomaterials, etc.) in Annex II of the Directive and in the BREFs would allow IED to be used as a lever to address these issues, as far as industrial activities are concerned. As regards form, the terms, thresholds and definitions used for the same concept in the various regulatory texts must be similar so as not to create ambiguity and differentiation and to facilitate implementation.

This could also be achieved through incentive schemes (quotas, taxes, market security, etc.) for companies to gradually eliminate the most dangerous substances from their production, emissions, etc. by also integrating the notions of essential uses.

1.5. Product/waste interface

The French authorities stress the importance of ensuring consistency between the objectives of protecting human health and the environment with regard to chemicals on the one hand, and the need to promote the circular economy and to achieve the objectives of the European policy on recycling on the other.

The French authorities consider that it is particularly important to make progress at European level in order to improve the conditions for such consistency, which are not currently met. As such, it is essential that the present Commission consultation leads to concrete actions and results.

It is important to note that the hazardousness of a waste is not directly linked to recycling: hazardous waste may be recyclable and recycled, and conversely non-hazardous waste may not be recyclable.

The French authorities have strong reservations about the practice of differentiated tolerance thresholds for the presence of hazardous substances depending on whether or not the products or materials come from recycling processes, and would prefer an approach by use and type of exposure. The French authorities recommend the development of methodological tools and databases relating to the positive externalities of the circular economy, in order to enable socio-economic experts in particular to extend their assessments beyond the immediate environment of the companies or markets targeted by the regulatory actions. Such an approach could only be envisaged on a case-by-case basis and only if it is based on uses and types of exposure that guarantee a high level of protection for the health of operators, users and the environment. In general, it is important to establish as far as possible similar requirements for virgin and recycled materials in order to ensure an adequate level of protection of health and the environment.

The French authorities therefore consider it essential to establish similar requirements for the product/waste interface:

1- To facilitate initiatives to make data available by producers and importers of articles on their content of SVHCs (which is a European regulatory obligation) or other dangerous substances within the meaning of the CLP Regulation;
2- To promote standardisation and innovation actions for the characterisation and improvement of the performance of recycling processes with a view to reducing or controlling the levels of hazardous substances included in the resulting materials.

The French authorities are in favour of the introduction of end-of-life provisions in the conditions of production, placing on the market and use of a substance so that industrialists can demonstrate that dangerous substances, which have been used in the production of products, will not be released into the

environment throughout their life cycle and during their recycling. This will facilitate the transition to a safe circular economy consistent with its objectives.

Furthermore, the French authorities consider that information throughout the supply chain and consumer information should be strengthened. The application of Article 33 and Article 7(2) of the REACH Regulation must be strengthened in order to ensure a reliable flow of information in the supply chain and to ensure that the authorities have sufficient information on the use of substances in Annex XIV of REACH in imported articles to be able to assess the relevance of regulatory measures at the waste stage.

The French authorities consider that consumers should have access to information on SVHCs in articles as soon as they purchase them. Initiatives such as the Life Ask REACH application and database and the implementation of Article 9 of the Waste Framework Directive are moving in this direction.

The French authorities would like this approach to be extended to all products containing dangerous substances within the EU. In this respect, they draw the attention of the European Commission to the political guidelines that the French Parliament has voted in the framework of the law on the fight against waste and for a circular economy. This law provides for the obligation for those placing products on the market to make the list of all products containing dangerous substances easily and freely available.

1.6. Avoiding unfortunate substitution and deleterious deported effects

The French authorities note the emergence of numerous alternatives to the most dangerous substances. However, the French authorities wonder about the societal, social, and environmental and health costs of the development of these alternatives. They indicate that for a significant number of these alternatives, a lack of data on toxicity is noted at the time of marketing and that it is only years later that these substances can be recognised as dangerous by regulations, whereas the proximity of chemical structures could have constituted a sufficient warning (cf. § 1.3.C).

The French authorities ask the European Commission to provide for an integrated approach when assessing substances, particularly when they are developed as alternatives to hazardous substances. The French authorities consider that account should be taken not only of the final impact of the substances on human health and the environment but also of the economic, social, societal and environmental impact of this new production method (employment, wealth generated, relocation, extraction of raw materials, diffuse pollution accumulated throughout the production chain, impact on human health and the health of workers, etc.).

To enable this integrated approach to be applied, the French authorities are asking the European Commission to provide incentives (subsidies, training, support for R&D&I, etc.) to encourage the substitution of dangerous substances by substances that, in addition to reducing risks, have a comparatively favourable economic, social and societal impact.

1.7. Better protection for vulnerable people

The French authorities consider that the objective of the regulations must be to limit as far as possible the exposure of the environment and the population to dangerous chemical substances and thus to protect the entire population.

This general protection objective involves adapting assessment and management methodologies to the vulnerabilities of certain population groups (e.g. the maximum permissible doses are not necessarily the

same for an adult and a child, the concept of an exposure window must be taken into account when pregnant women are exposed).

The French authorities suggest to the Commission that it should take stock of the extent to which the concept of vulnerable persons is taken into account in the various regulations (existing definitions in some regulations), both in the regulatory texts and in the assessment methodology.

They also call on the European Commission to urgently review European regulatory texts based on a risk-based approach when they concern products that affect the general public such as cosmetics, toys and materials in contact with foodstuffs, so as to strengthen the protection of vulnerable persons on the basis of the latest available knowledge, and by implementing the simplified restriction procedures under REACH by also extending them to hazards complementary to CMRs.

1.8. Better protection for workers

In this unprecedented context of COVID-19, the French authorities are in line with the May 18, 2020 declaration by UN human rights experts on the importance of protecting workers against COVID-19 but also against chemical substances. This declaration recalls the worrying nature of workers' exposure to toxic substances: "Workers are exposed to a cocktail of toxic substances: from industrial chemicals to pesticides. Millions of workers continue to be forced to make the odious choice between their health and their income, and millions more are being poisoned without their knowledge or consent."

The French authorities note that assessments of exposure risks for workers are often based on incomplete knowledge or assumptions that do not reflect reality, thus minimising the impact on workers' health. They ask the Commission to improve the provisions on the protection of workers from hazardous chemicals.

1.9. Improving knowledge of impregnation and exposure to hazardous substances

The French authorities would like the Commission to increase knowledge of the impregnation of the environment and the population by dangerous substances. They consider that this data collection, carried out by certain Member States, would be more effective if it were carried out at European level with a view to improving the protection of citizens and the environment.

The French authorities would like the various databases on dangerous substances and mixtures (environmental contamination, impregnation of the population, economic activity, socio-professional category, practices, sectors - in particular agriculture, cases of poisoning reported by poison control centres, etc.) to be made available to the public.) to be cross-referenced in order to map and highlight spatial, temporal and socio-economic trends in environmental contamination by the most hazardous chemicals (CMR, PE, PBT, vPvB, POPs, sensitizers) and the exposure of the population to these substances. This brings us back to the issue of information exchange and availability. A single actor responsible for this theme could help build these databases. This should not be to the detriment of national programmes, but care must be taken to ensure that these programmes are compatible with European initiatives.

It will thus be a question of developing precise databases on the composition of chemical products, such as those of the European Poison Control Centres, with the same level of quality requirements for declarations by those responsible for placing them on the market, whatever the category (all products, cosmetics,

biocides, plant health, etc.), while respecting intellectual property and taking care to limit the workload for companies. The objective is to better understand the market for chemical products, to have tools to assess the exposure of populations and the environment to substances, and to know, monitor and combat the diseases or accidents they induce.

This also requires greater recognition of the scientists who make up the national agencies.

2. Strengthening European expertise

2.1. Independence of European agencies to restore public confidence

The French authorities consider that a strengthening of the regulatory framework on chemicals necessarily implies a high degree of transparency and independence of the agencies and scientific evaluation committees, in particular the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and the European Scientific Committee for Consumer Safety (SCCS).

The French authorities consider that the recommendations of the European Court of Auditors of 11 October 2012 should be fully implemented. They request a review of the implementation of these recommendations as well as a new audit of ECHA, EFSA, EMA and SCCS.

The French authorities identify a strong need for independent scientists able to assess the impact of new technologies and their products before they are authorised by the legislators. They therefore consider that independence is essential if the European agencies are to continue the crucial work they do with sufficient quality and credibility.

A precondition is that the European agencies receive stable and sustainable funding that corresponds to the level of activity they will justify. The French authorities propose that this funding should be provided both by the economic actors and by the Commission to ensure a stable budget for the agencies. The French authorities consider this step to be imperative in order to speed up the identification of harmful chemical substances.

Furthermore, the ethical rules adopted at European level should be evaluated and, where necessary, harmonised. They should also be compared with the rules put in place within the Member States in similar structures or agencies. This feedback would make it possible to objectify the difficulties in finding experts who are both competent and independent.

2.2. Independent supplementary assessments

The French authorities reiterate their support for the creation of a European mechanism to enable the European agencies (ECHA, EFSA, EMA, EEA, OSHA), or the network of national agencies in coordination with the European agencies, to carry out independent studies on substances that may be dangerous. This has already been included for EFSA in the revision of Regulation 2009/1381 on General Food Law. This work consists, in exceptional cases, justified by strong scientific controversies for example, of an impartial assessment of the evaluations provided by the industrialists, without calling into question the general principle according to which marketers are responsible for producing the data on which the application for authorisation is based. This work would therefore fall fully within the current scope of competence of the agencies and committees responsible for examining the dossiers submitted by industry. This work could be financed by an increase in the funding received by the agencies from manufacturers under the chemicals regulations.

2.3. Single evaluation platform

This platform should strengthen cooperation and coordination between the European evaluation agencies and the national agencies. Hazard identification should not differ between sectors and regulations, common guidelines should be adopted for risk assessment, in particular for biocide and plant protection products, taking into account the latest scientific findings and chronic exposure.

The French authorities note that the crossover between multiple sectorial and horizontal regulations can sometimes be detrimental to the consistency of the assessment and the control of public expenditure. The French authorities propose to the European Commission to set up an inter-agency governance structure, including at least ECHA, EFSA, EMA and EEA, in order to promote inter-agency exchanges and improve the coordination and coherence of the assessment between the different agencies and the regulations for which they are competent, thus optimising resources by avoiding, for example, assessing the same substance several times.

3. Strengthening controls

The French authorities stress the importance of strengthening controls to ensure that articles and foodstuffs entering the European market comply with EU requirements and also to check that European regulations are respected and implemented within the European territory. This means securing the resources given to the national authorities responsible for the control of chemicals (in particular in articles and foodstuffs) and also strengthening cooperation between the customs services of the various Member States, and within the Member States, by reinforcing cooperation between the various control services.

The French authorities are also in favour of the creation of a European control force with EU sanctions tools and with the legal means to implement these sanctions, and which can be mobilised on subjects where European expertise is required. This monitoring force could thus be the counterpart on the environmental aspect of the European Labour Authority (ELA). In particular, it could use its strike force to organise, coordinate and take part in European-wide punch actions on subjects that are topical or of common concern to several Member States.

This new organisation should also take a position on the control of e-commerce and be a driving force for the development and implementation of new tools and methods. The French authorities have noted an increase in infringements of chemicals regulations via e-commerce platforms.

In addition, the French authorities again draw the Commission's attention to the territories benefiting from a customs union with the European Union. European regulations, in particular the "F-gas" regulation, are not necessarily applicable there and companies located in these territories may place substances on the European Union market without having to comply with the provisions of EU regulations, in the case of HFCs this includes the obligation to comply with a quota. In this example, the Customs Union introduces the possibility of importing substances into the European Union by circumventing the quota system. The French authorities consider that this is a very serious flaw in the system set up at European level, which must be corrected.

4. Giving impetus to research

In view of the uncertainties regarding the hazardous properties of substances, in particular endocrine disrupters, cocktail effects, the influence of the exposome and epigenetics, the French authorities consider that the strengthening of European resources dedicated to fundamental research into environmental health is a priority. Epidemiological studies aimed at monitoring populations, using the "exposome" approach, coupled with applied health research, are also essential to make progress in understanding causal relationships. They will make it possible to better take into account the effects of hazardous substances and better manage them in order to reduce exposure and risks.

The scientific community as a whole agrees that major research efforts are still needed. The Commission presented its Horizon Europe programme for research and innovation for the period 2021 to 2027. The French authorities welcome these guidelines, which should be strengthened. They consider that the health-environment issues present in the four pillars of the Horizon Europe programme ("Scientific excellence", "Global issues and European industrial competitiveness", "Innovative Europe" and "Widening participation and strengthening the European Research Area") and in the partnerships should be explicitly mentioned and be the subject of dedicated funding commensurate with the issues at stake. Ambitious funding should be dedicated to the Partnership for the Assessment of Risk from Chemicals (PARC) partnership envisaged under Horizon Europe, for which France (via the Anses) has applied for coordination.

The French authorities call on the European Commission to promote, within the framework of these research programmes, the improvement of knowledge, in particular:

- on the levels of impregnation of populations, in particular by emerging pollutants;
- on cocktail effects and synergies between chemicals;
- on epigenetics;
- on the exposome;
- on the development of predictive toxicology and ecotoxicology tests, in accordance with the "3Rs" rule;
- on the modes of action of endocrine disruptors beyond the EATS axis alone (Estrogenic, androgenic, thyroid and steroid).

The French authorities underline that it is also crucial to share and make the most of research data and to set up an early warning system to identify as quickly as possible the dangers of a new substance that would be registered via REACH and present on the European market.

Furthermore, the French authorities consider that research must be able to contribute to the effort to substitute dangerous substances. To this end, European research funding mechanisms must be fully mobilised to participate in this innovation effort, to mitigate the risks inherent in the gradual disappearance of dangerous substances and to give Europe a competitive advantage in sustainable chemistry and industry.

5. Better inform citizens

The issue of chemicals and their hazardousness is a growing concern for European citizens, but also an issue that remains complex and poorly understood. Information and advice to the public is therefore essential.

The French authorities would like actions to be put in place to inform the general public, particularly sensitive groups, directly via information relays.

The French authorities consider that consumers should have access to the information on SVHCs contained in the articles as soon as they purchase them. Initiatives such as the Life Ask REACH application and database and the implementation of Article 9 of the Waste Framework Directive go in this direction. This

information should not be limited to SVHCs for categories of articles exposing the general public (e.g. toys). The establishment of communication tools for the general public at European level is a strong act for the appropriation by citizens and industrialists of the work carried out at European level to protect the population. The French authorities consider that direct information and the possibility of choice for the citizen are decisive in enabling them to control their exposure to dangerous substances. The French authorities therefore consider that the Commission should consider the possibility of introducing compulsory labelling to indicate the presence of such substances.

The French authorities inform the European Commission that the French Parliament has decided to strengthen, within the framework of the law of February 2020 on the fight against waste and the circular economy, the information provided to consumers as soon as a consumer product contains one or more dangerous substances. The French authorities would like this provision to be taken over at Community level and is not limited to SVHCs.

6. Promoting high European standards at international level

The French authorities consider that free trade agreements should promote the best standards, particularly those relating to health and the environment. The French authorities therefore believe that this strategy on chemicals should be used as an opportunity to ban the production and export of chemicals, in particular pesticides, which are banned in the EU in view of their harmfulness to the environment and human health. The French authorities consider it unacceptable that dangerous substances banned for use within the European Union can be produced on European soil for export outside the EU. This is the case of atrazine, a substance with herbicidal properties and very persistent in the environment, which has been banned in the European Union since 2003.

In addition, the French authorities point out that some of these substances banned for use on the European market still circulate there via products imported from third countries. Paradoxically and without being informed about it, citizens find themselves exposed to a risk that the Union is seeking to prevent. This situation does not make it possible to meet our demand for the protection of European citizens and creates a distortion of competition that is harmful to our industrialists. The French authorities are therefore calling for more control by the European Commission, particularly on the presence of banned chemicals in imported products and the introduction of provisions in European regulations, particularly the PIC regulation on the import and export of dangerous chemicals, in order to avoid the distortions sometimes induced by free trade agreements.

The French authorities want EU environmental standards to be respected within the framework of trade agreements and more broadly in trade with non-EU countries, on the basis of the best environmental.

They are asking the Commission to implement a simplified restriction procedure in REACH for the most dangerous substances, and also want an authorisation procedure in REACH for the presence of SVHCs in articles produced in Europe as imports, as a priority for the substances in Annex XIV and for certain categories of articles to be defined and for which there are exposure issues.

They would like to reiterate their support for the measure in the Biocidal Products Regulation which bans the placing on the market of articles treated with substances not approved in Europe.

It should also be ensured that these provisions do not create difficulties for companies subject to international competition and, if necessary, arrangements should be put in place to remedy this.

7. Specific Expectations for Certain Regulations and Substances

7.1. Improvement of data quality in REACH registration dossiers

The French authorities take note of the work in progress to bring registration dossiers into compliance, including manual compliance checks, to ensure the timely update of registration dossiers and to update Annexes VI to XI of REACH to provide registrants with the most transparent and comprehensible reading possible on information requirements and cases where testing can be waived.

The French authorities believe that the regulatory framework should clearly indicate that non-compliance will eventually lead to the revocation of registration numbers and therefore to the revocation of the right to place the substance on the market, according to the "no data - no market" principle.

The French authorities also consider that registrants should be obliged to update their registration dossiers at least every 3 years to ensure that the most recent and relevant data are evaluated. This also ensures fair competition between marketers of the substance and the alternatives developed.

The French authorities wish to stress the importance of providing the public with easily accessible information on the data of registered substances and the deadlines for updating them, in order to encourage companies to meet the registration requirements. Therefore, the French authorities consider that, as a minimum, the competent authorities of the Member States should have easy access to the full study reports of the marketers. The principles of data access enshrined in the 'Transparency Regulation' of the General Food Law must also be taken into account for data on chemicals.

Finally, the French authorities stress the importance of strengthening the information requirements on chronic toxicity to aquatic organisms. Annexes VIII and IX stipulate that long-term aquatic toxicity testing should be considered if the chemical safety assessment indicates the need to further investigate effects on aquatic organisms. However, very few long-term aquatic toxicity tests have been carried out under REACH. Thus, the current wording under REACH (i.e. the need to consider) does not lead to appropriate action by registrants. The requirements therefore need to be made clearer and more enforceable to achieve a high level of environmental protection.

7.2. Competence of the Board of Appeal of ECHA

The French authorities consider it legitimate to give companies a legal possibility of appeal against any decision taken by ECHA, as is the case today.

The REACH Regulation establishes an internal Board of Appeal within ECHA, which decides on certain decisions taken by the Agency detailed in Article 91 of the Regulation. However, the limited scientific capacity related to the current composition of the Board of Appeal should be recognised. Therefore, it should not be left to the discretion of the Board of Appeal, except on procedural grounds, to reject decisions taken by the Agency after unanimous agreement of the Member State Committee and experts from all Member States.

Indeed, in cases where the Member State Committee has not reached unanimous agreement and the Commission with the support of the REACH Committee takes a final decision, appeals are made directly to the Court of First Instance of the European Union.

Limiting the scope of the Board of Appeal to procedural grounds would harmonise access to appeal and ensure that there would be no different approach to the same type of decision depending on whether the Agency or the Commission took it.

7.3. Endocrine disruptors

The French authorities would like to see the EU regulatory framework on chemical substances evolve in order to take due account of endocrine disrupters.

The French authorities consider that endocrine disrupting properties are of equivalent level of concern to the hazards of greatest concern (carcinogenic, mutagenic and toxic to reproductive organs, CMR, and persistent bioaccumulative and toxic, PBT, and very persistent and very bioaccumulative, vPvB). This approach of equivalence between these hazards of greatest concern is justified by the health and environmental challenges posed by endocrine disruptors. This approach is consistent with the most recent regulations that have placed at the same level CMRs and endocrine disruptors together with PBTs, vPvBs.

The problem of endocrine disruptors has been known since the 1990s without any frank action from the European Commission, and citizens' mistrust of the European institutions will only increase. Therefore, the French authorities are asking the European Commission to implement without delay a regulation on endocrine disruptors that is harmonized and valid in all sectors and to apply the precautionary principle in order to minimize the exposure of the population and the environment to these substances.

The French authorities recall their requests expressed during the consultation on the fitness check of the regulations on endocrine disrupters. They consider it necessary to establish, as is the case for CMRs, a single definition of endocrine disrupters, which should be

- included in a horizontal regulation (CLP as a priority);

- broken down into 3 categories according to the level of evidence ("known", "presumed" and "suspected" endocrine disrupters, as is the case for CMRs, in order to adapt risk management measures according to the level of evidence).

The "suspected" category is crucial for substances with an ED mode of action with an adverse effect but with an insufficient level of evidence to be classified as "known" or "presumed". With these three categories, risk management can be adapted according to the level of evidence and the precautionary principle applied.

The French authorities consider that the distinction made between endocrine disruptors for humans (of equivalent concern to CMRs) and endocrine disrupters for the environment (of equivalent concern to PBTs and vPvBs) can be maintained. Indeed, this distinction may be useful as some regulations currently only assess risks to human health (e.g. cosmetic regulations), or risks to the environment. In general, the French authorities would like to see the regulations on chemical substances in the future clearly organise an assessment of the risks to human health and the environment. However, this distinction will eventually have to disappear in order to integrate a common "one health" approach into the regulations.

With regard to risk management, the French authorities support a principle of prohibition unless an exemption is granted for endocrine disruptors, as is already the case for CMRs in most regulations on chemicals, in particular in the regulations on biocidal and plant protection products. Possible exemptions are to be discussed in the light of different criteria: the level of evidence ("known", "presumed",

"suspected"), the population and environment exposed and the notion of essential uses. The French authorities consider that this approach must be taken into account when managing substances as dangerous as endocrine disrupters.

The French authorities thank the Commission for the work undertaken within the framework of CARACAL on the REACH annexes and the inclusion of tests for endocrine disrupting effects in the regulations, work to which ANSES contributes. The French authorities point out that it is necessary to have access as soon as possible to a summary of the tests for identifying endocrine disruptors available at OECD level. They will also indicate that this summary should highlight the courses of action that are not taken into account (or too little taken into account) by existing tests, so that risk management can be adapted accordingly. This summary should be compared with the tests currently required in REACH and BPR and PPPR and the testing requirements should be updated.

In particular, the French authorities request the inclusion of a battery of in vitro tests to enhance the identification of suspected endocrine disrupters (similar to the one established for genotoxic properties) in the data requirements of Annexes IX and X of REACH. Such a battery of tests would provide - together with the relevant non-experimental methods - relevant information that could be used to identify the substances to be evaluated in order to conclude whether they are endocrine disrupters.

7.4. F-gases

Hydrofluorocarbons (HFCs) are greenhouse gases, mainly used for air conditioning and refrigeration, whose global warming power can be up to 15,000 times greater than that of CO2. They account for 10 to 15% of greenhouse gas emissions worldwide and 5% in France. According to estimates, their elimination would allow a 0.5°C decrease in global warming.

In order to face this major climate challenge, Europe wished to play a pioneering role by adopting in 2014 the (EU) regulation no. 517/2014 on fluorinated greenhouse gases (the so-called "F-Gas" regulation). One of the main objectives of this regulation is to regulate, through a quota system, the progressive reduction of HFC consumption ("phase down"), with the objective of reducing the quantities placed on the market by 80% by 2030 compared to the level in 2015.

However, the effectiveness of this regulation in the fight against climate change is compromised due to the observed increase in illegal trafficking of HFCs from third countries and the particular situation of certain countries that have a customs union with the European Union.

The French authorities welcome the work already undertaken by the Commission to improve cooperation between the Commission's Directorates-General CLIMA and TAXUD and the planned integration of the HFC quota system provided for in the F-gas Regulation into the future "Single Window" customs control software by 2020. The number of quotas allocated to each importer will thus be counted in real time and the effectiveness of controls will thus be reinforced.

More generally, the French authorities are in favour of revising the F-gas Regulation in order to make the system for controlling imports and exports of products containing HFCs more robust. They call for a system, which goes beyond real-time, monitoring, in line with the requirements laid down in the Kigali amendment and the Commission's commitments3 made when the previous F-gas Regulation, dating from 2006, was revised.

7.5. Nanomaterials

The French authorities thank the Commission for the revision of the REACH annexes voted in April 2018 and consider that this is a crucial first step to take into account the specificities of nanomaterials. The French authorities also welcome the work undertaken by the Commission on Annex II of REACH to comply with the Global Harmonized System in order to make the European regulatory framework on nanomaterials more protective for European citizens.

Amendments to the annexes of REACH came into force in January 2020; the French authorities recall that the Commission, ECHA and Member States must now work in a coordinated manner to ensure that registration dossiers have been updated to take into account the specificities of nanomaterials, where relevant.

The French authorities indicate that there is a need to adopt a harmonised and legally binding definition of nanomaterials common to all regulations. This would be beneficial to ensure the proper implementation of regulations by economic actors and public authorities, facilitate controls on the application of regulations and promote the coherence of public policies on chemicals. To this end, the French authorities are asking the European Commission to launch as soon as possible a public consultation on a legally binding general definition of nanomaterials, valid for all relevant European regulations.

The French authorities point out that they have set up a register in 2013 for the declaration of substances in the nanoparticle state and that they would like this register to be extended to the EU level.

7.6. Biocidal and plant protection products

The French authorities consider that the subjects related to biocides and pesticides should be included in the reflection on the strategy, stressing the opportunity of a revision of the Directive, which, according to the French authorities, should include biocides.

The French authorities ask the Commission to identify the links to be improved between these regulations and REACH and CLP as the subject of co-formulants or treated articles may have been a sign of a lack of legibility and an ineffective sharing of responsibility.

In particular the most hazardous co-formulants will only be effectively banned if the competent authorities under REACH or CLP initiate harmonised classification and SVHC identification dossiers quickly.

In addition, the creosote dossier has shown the difficulty to act quickly to control the risks of treated wood, due to the overlap of the biocide and REACH regulations.

Appendix - Comments from French Authorities related to REACH review report presentation

1. Context:

REACH Regulation provides for obligation to review every five years the progress made in achieving its objectives. The second review was conducted in 2017, in parallel with the carrying out of an evaluation of the other chemical Regulations (Fitness check evaluation) in the framework of REFIT program (Fitness and Performance Regulation). **On 5 March 2018 the European Commission published its REACH Regulation evaluation report; there is also an associated communication.**

2. Acknowledgements:

French Authorities thank Commission for the work accomplished, both for the evaluation which has been carried out here and for all the work accomplished since the adoption of the Regulation.

3. Comments from France.

3.1. General judgement

French Authorities share the positive opinion of Commission on progress made in implementing Regulation and expected benefits for human health and environment, although still below initial expectations.

They also share issues and priority questions identified by Commission in relation to the existing package and the need to put in place actions. **They wish a schedule for these actions to be established as well as a detail of how they will be implemented**

In the framework of the alignment of the Regulatory procedure with control (PRAC) on the post-Lisbon procedures, it was noted that REACH Regulation should be removed from the scope of the exercise and that the discussions should be carried out in the framework of the REFIT process.

The Commission's report concludes that there is no need to modify the package. However, the French Authorities consider it necessary to know the Commission's analysis and intentions as regards bringing the Regulation into conformity with the Lisbon Treaty.

Moreover, French Authorities regret that the conclusions of the report do not deal in detail with the reflection on a better consideration of emerging risks (endocrine disruptors, nanomaterials, cocktail effects) which is sometimes delayed due to the required levels of evidences. which are not suitable for these issues. To this end, they recall that it is important for health agencies to be able to make a clear decision on the mobilization of the precautionary principle when the finalization of the hazards assessment meets with uncertainties or delays too long.

France's positions in the framework of reflections on the role of European agencies and, in general, on the evaluation and management of the risks of chemical substances in Europe were also expressed in last October environment council[1].

3.2. Examination of Commission proposals.

Action 1: Encourage the update of registration dossiers.

European Chemicals Agency commissioned a study in 2017 to register information on the factors, obstacles, costs and benefits of updating REACH[2] registration dossiers, the results of which suggest that more clarity is needed on how the registration process works and what needs to be updated and by whom. The Commission can usefully use this basis to make suggestions for improvement.

It has been noted that the quality of the registration dossiers is clearly insufficient, and that after the REACH 2018 deadline, a particular attention should be paid to updating dossiers, adding requirements for nanomaterials, and good consideration of polymers.

Action 2: Improve evaluation procedures

French Authorities consider that lack of conformity of a large number of registration dossiers is a major obstacle to proper functioning of REACH Regulation, and in particular for assessment of dossiers and substances and agree with Commission on the priority character to remedy this.

The Commission proposes, when it is appropriate, to apply different evaluation procedures in parallel.

French Authorities propose that, in general case, dossier conformity assessments (CCHs) can be finalized before substance evaluation (SEV) so that these can be carried out on the basis of registration dossiers exhaustive and conform, especially in terms of substance identity.

However, if the information is sufficient to finalize a SEv, it essential to not wait through the CCH procedure. This will require coordinating and sharing information between ECHA in charge of the CCH and the Member State in charge of SEv.

Commission also advocates systematising the substance group approach with similar properties rather than individual substance. French Authorities support this approach, the aim of which is to improve the consistency of evaluations between substances of a same group.

In practical terms, the pilot collaborative approach conducted in 2017 shows that the exercise can in some cases be time-consuming when it is found, during evaluation, that the group approach is ultimately not relevant and that there will be no conclusion for the whole group (case of substituted diphenylamines evaluated by France and Slovenia).

1 The Environment Council of October 13, 2017, allowed to call for the adoption of a comprehensive and readable strategy on chemical exposure ("strategy for a non-toxic environment") and to strengthen confidence in environmental mechanisms. assessment and authorization of chemical substances, in order to restore trust between citizens and decision-makers at European level, in particular by deepening the transparency of processes and the independence of studies carried out by the agencies.

2 https://echa.europa.eu/documents/10162/22931011/study_drivers_and_obstacles_reach_clp_updates_en.pdf/

Action 3: Improve the operability and the quality of extended safety data sheets

French Authorities are in favour of the actions proposed by the Commission. The inclusion of minimum requirements will notably improve the quality of documents and facilitate control measures.

Action 4: Monitoring of substances of concern in the supply chain

French Authorities consider it desirable to facilitate initiatives in favour of the provision of data by producers and importers of articles as regards their content of SVHC (which constitutes an European regulatory obligation) or other hazardous substances within the meaning of the CLP Regulation.

French delegation considers that this topic is important in the context of the REACH / waste interface discussions, since SVHC identification allows a traceability of substances of most concern. SGAE ITEC / 2017/07711[3] note recalls the French positions on this subject.

Action 5: Promote substitution of SVHC

Substitution of SVHCs is an essential step that must be promoted and facilitated. SVHC list is one of the major drivers of substitution, as noted in the latest reports by ECHA and Commission, and Annex XIV has led to an improvement in terms of risk management as noted in the last report of the Commission.

The candidate list is, since its creation, regularly updated. In the process of innovation that contributes to substitution, economic actors need visibility on both substances to be replaced and substances that could be proposed on candidate list. As French delegation pointed out, SVHC 2020 roadmap fulfills this objective of visibility for companies, which can know very well in advance when a Member State or ECHA are working on possible measures for management of a substance.

French Authorities recall their implication to improve communication and structuring of the sectors with aim of substitution.

Moreover, in addition to substitution, French Authorities consider that REACH Regulation should, because of considerable resources it mobilizes for its implementation in particular, have a greater impact on other chemical or sectoral regulations.

Substances identified as substances of very high concern (SVHC) should, for this purpose, be specifically addressed in relevant regulations. Thus, in the REACH Regulation, the question of extending the article of the regulation allowing generic restrictions for carcinogenic substances 1A and 1B following CLP to SVHC substances could arise.

This position had already been expressed by European Parliament in its resolution on food containers.

French Authorities recall their involvement in improving the communication and structuring of the sectors with aim of substitution.

3 Note from the French Authorities on the European Commission's consultation on the interface between the regulations on chemicals, products and waste.

Action 6: Simplification of authorization procedure to make it more operational

The latest Commission report shows that authorization procedure has achieved its objectives **for substances actually included in Annex XIV**, with significant benefits for health and environment.

French Authorities point out that the inclusion of all relevant substances in the SVHC list and in Annex XIV is a constant political commitment, in particular via SVHC 2020 roadmap, and necessary to achieve the objectives of the Regulation. The acceleration of the process should also take into account the ability of manufacturers to build authorization files and to carry out searches for substitutes for SVHCs.

French authorities would like to speed up the overall process, noting the long process of inclusion in Annex XIV, which means that all substances that should be in Annex XIV are not yet. In this respect, France would like simplified applications for authorization in certain specific cases to be put in place; France wishes also model applications for authorization adapted to certain sectors to be developed. France is also committed to helping to ensure that all relevant substances are included in the SVHC list.

The French Authorities consider that the current situation does not make it possible to achieve the REACH objectives for the protection of health and environment with regard to substances of very high concern.

In this respect, French Authorities recall that Risk Management analyses (RMOAs) are informal preliminary analysis tools whose purpose is to help decision-making upstream of implementation of a management measure. risks, not to be confused with the risk analyses (RA) and socio-economic analyzes (SEA) carried out as part of implementation of these management measures. These RMOAs analyzes are nevertheless an important tool. As a result, ECHA's RMO models should be followed by all Member States and, as is done in France, a public consultation should be conducted as part of these analyzes.

Optimum functioning of the procedure will favourably consider inclusion of new substances in Annex XIV.

Action 7: Early socio-economic information for possible regulatory measures

French Authorities stress that socio-economic analysis is, with risk assessment, at the heart of risk management measures of REACH Regulation (restriction and authorization). Its quality is highly dependent on scientific methods and data that are sometimes perfectible because they depend on a relatively recent scientific discipline in the fields of health and the environment and information requiring a thorough knowledge of industry and its technologies. This knowledge raises the question of the compatibility between a specialized expertise in this area and the essential obligation of absence of conflict of interest.

French Authorities consider that the present evaluation of the REACH Regulation would be an opportunity to question the appropriateness of reinforcing efforts to promote the socio-economy in general and to enable Socio-Economic Analysis Committee (SEAC) to use, as necessary, outside expert assessments, without slowing down procedures.

Actions 8 and 9: Improve restriction procedure and involvement of the Member States

It seems essential to underline the important mobilization of the Member States to establish the restriction dossiers with a demanding burden of proof.

French Authorities highlight the onerousness required for restriction dossiers, which does not allow to achieve the REACH objectives of protecting human health and environment by dissuading public authorities from providing restriction dossiers, which mobilize considerable resources.

French Authorities are in favour of generic restrictions for CMR in consumer products. They want an extension to the endocrine disruptors of this procedure.

Otherwise, French Authorities ask Commission to consider a simplified procedure for the prohibition of SVHC in Annex XIV in imported articles, as is the case for articles produced in Europe, by fairness for European economic actors, taking into account security of supply also for certain sectors such as Defense.

Action 10: Framing application of the precautionary principle

French Authorities support the Commission's requests for substances for which scientific information is not sufficient to conclude on the risk assessment.

The clarity of the agencies' advices should be improved so that they are well-identified in their risk assessments where the precautionary principle is to be mobilized by risk managers.

Action 11: Interaction between authorization and restriction

French Authorities consider that an improvement of the system is necessary in order to avoid a distortion of competition between the ban on the use of Annex XIV substances for companies located in Europe and the possibility for companies based outside Europe to import into the European territory products for which the said hazardous substances have been used.

French authorities propose to study in this sense the combined use of authorization and restriction procedures with a simplified procedure to obtain prohibitions on articles (imported in particular) containing Annex XIV substances, to protect the industry, the security of supply also for certain sectors such as Defense.

Action 12: Interface between REACH and SST regulations (OSH)

French authorities share the Commission's opinion on the need to clarify and reinforce interactions between REACH and SST legislations.

In this sense, the coordination between the authorities in charge of these two regulations and the sharing of available tools proposed in points 12 (1) and 12 (2) are essential. ECHA's RIME+ platform could be the venue for such an exchange

Action 13: Strengthening control

French Authorities are of the opinion that, beyond clarifying and strengthening the role of the REACH supervisory authorities and the customs authorities in the application of REACH, an essential element of the proper application of the Regulation is to ensure homogeneity of the means and methods of control between Member States. ECHA Forum will have to continue working on this task.

The establishment of relevant monitoring indicators proposed by the Commission in 13 (2) must also go in this sense.

Action 14: SME support and Action 15: royalties and the future of ECHA

French Authorities share these proposals. However, with regard to royalties and costs, financing options selected should be careful not to impact to a greater extent the economic actors who have had to cope with a cost of the device higher than forecast, even if these costs are largely compensated health and environmental benefits of implementing Regulation.

Action 16: Review of registration requirements for low tonnage substances and polymers

French Authorities note the ongoing work of the Commission on the topics of polymer registration and information requirements for low tonnages. On this second point, they share the latter's point of view on the need to assess affordability of the increase in information requirements in the lower tonnage bracket for SMEs.

They consider that a thorough examination of cost issues, in particular for SMEs and registration of substances used in small quantities, is necessary. These costs have had consequences in terms of product abandonment, outsourcing of products outside the EU, and the reduction of innovation capacities, which are necessary to carry out substitution actions for the substances of most concern.