The Economics Interface

A review of the analyses of alternatives presented in recent Annex XV restriction dossiers

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Introduction

The Restriction Task Force recommended that ECHA should examine best practices in the conduct of analysis of alternatives (AoAs) supporting REACH restrictions or derogations thereof. This note presents the findings of a short review of recent restriction dossiers and their AoAs undertaken for ECHA order ECHA/2020/387 implementing the framework contract ECHA/2019/191.

The objective of this review was to provide best practice advice to potential dossier submitters by reviewing recent REACH restriction cases with a specific focus on their AoA. Specifically, the work was requested to:

- review recent REACH restriction cases (incl. derogations);
- find best practice examples for different parts of the AoA; and based on that
- distil where possible some recommendation for Dossier Submitters (DSs).

The restrictions selected by ECHA for review were the following:

- The use of lead gunshot over wetlands;[1]
- The use of D4 and D5 in wash-off personal care products (PCPs);[2]
- The use of lead as a stabiliser in PVC articles;[3]
- The use of bisphenol A (BPA) in thermal paper;[4]
- The use of four phthalates (Article 69(2)).[5]

There were no strong criteria for selecting these particular dossiers. All had been through the entire opinion-making process, and all were considered to have covered contexts where the AoA had a reasonable scope, but there was no suggestion that the dossiers were either 'good' or 'bad' examples of AoA practice. Because one of the objectives of the review was to provide advice to DSs, it was decided that the review should focus on the Annex XV dossiers initially proposed by the DSs, rather than any version of the background document developed by the Committee for Socio-Economic Analysis (SEAC). It would have been useful to compare the initial Annex XV dossiers with the resulting background documents to see what had changed, but this would have been a major undertaking beyond the scope of resources available for the study. In addition, it would not necessarily have been possible to understand why any changes

[1] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180c0ac38
[2] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18050cc56
[3] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180a40af7
[4] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18051ba62
[5] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1806e7a36

had been made and whether they were due to deficiencies or otherwise in the original dossier AoA.

The rest of this note is organised into a number of sections:

1. The identification of the different reasons for undertaking an AoA. This is done via reference to the official ECHA guidance on undertaking restrictions, [6] but also at a higher level on the basis of how AoAs in restrictions and more broadly have been used in practice. These reasons affect how the AoA might best be undertaken, but are also not necessarily consistent;
2. A discussion of howAoAs might best meet its various objectives;
3. A consideration of the various constraints faced by DSs which might make it more difficult for their AoAs to meet their various objectives;
4. An examination of the AoA of each of the selected restrictions to explore these issues.

Reasons for undertaking AoAs in restriction proposals – The ECHA restrictions guidance

To think about what an effective AoA might look like, it is useful first to understand what the reasons for undertaking an AoA in a restriction proposal might be. In the ECHA guidance on preparing restriction dossiers, Section 5 states that the requirement to document the available information on alternative substances and techniques has the following overall aim:

> [T]o provide information for the analysis of whether the equivalent function provided by the substance can be obtained by other substances or techniques and for assessing the net impact of the proposed restriction to the human health and the environment. This will facilitate in defining a proportionate restriction that is targeted to the identified risk.

To this apparently rather straightforward end, the guidance suggests the information on alternatives should include, first:

- A description of the use and function of the substance
  - the specific technical performance requirements for the function;
  - the quality, durability or end product performance-related role of the substance; and
  - its economic importance in terms of reduced costs.

Once the functions provided by a substance have been described, alternative substances and techniques that meet the equivalent function or make the original function redundant, i.e. alternatives that are technically feasible, can be more easily identified. In collecting information about alternatives, questions to be considered include:

- Is the alternative technically feasible and available?
  - For which uses of concern is an alternative technically feasible?
  - Would adoption of the alternative require R&D, or changes to processes etc?
  - How long might adoption take?
  - Is the alternative available in sufficient quantity (appropriately defined) to replace the substance?

[6] https://echa.europa.eu/view-article/-/journal_content/title/guidance-for-the-preparation-of-an-annex-xv-dossier-for-restrictions

- Would transfer to the alternative substance or technique result in reduced overall risks to human health and the environment?
- Is the alternative economically feasible?
  - What would be the net compliance costs?
  - Could different actors afford the alternative and pass through any additional costs?

The layout of the ECHA guidance means that is not immediately stated how the information collected through the analysis of alternatives should be used in the restriction. However, at various stages in the document, its use is referred to in:

- The setting of derogations (Section 5.1.3), in particular that the 'main reasons' for including derogations are related to (*inter alia*):
  - Technical considerations (when it is not possible to produce the end product or acehive the same functionality by using an alternative);
  - Human health considerations (when the alternative would pose a greater risk than the substance of concern);
  - Economic considerations (the use of the alternative would result in significant economic impacts);
  - Regulatory and contractual considerations (e.g. a derogation would be required to allow regulatory approval for an alternative);
- Identification of possible other Risk Management Options (RMOs)
  - Available information on alternatives may indicate that RMOs other than a restriction would be more suitable for controlling the identified risk from uses for which no alternatives are available
- Assessment of RMO effectiveness, for instance:
  - Do the alternatives required due to the initial restriction cause other risks to the human health or the environment?
  - Does the initial restriction ensure a good balance between costs and benefits and is it cost-effective.

The ECHA guidance concludes that bringing the risk reduction and proportionality aspects of the effectiveness of the initial restriction together might show that refining of and decision making on the restriction proposal would benefit from a SEA, although a SEA is not as such a mandatory requirement of the Annex XV dossier (but all Annex XV dossiers submitted so far have included a SEA). There is, of course, a separate guidance document dedicated entirely to SEA in restrictions, and it is outside of the scope of this note to consider that.[7] However, from Section 5.6 of the restrictions guidance, it can be inferred that the SEA is a 'bringing together' of the information gathered in the rest of the dossier, 'aggregating' it up a Community level to give an overall assessment of the impacts of the restriction proposal. The suitability of possible alternatives affects how companies are likely to respond to a restriction and hence what the risk impacts and net costs of the restriction might be, and therefore the AoA is clearly directly relevant to the SEA and the restriction dossier as a whole. Exactly how the information might fit into the SEA and the restriction justification is considered in the following section.

[7] https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf

Reasons for undertaking AoAs in restriction proposals – Practical experience from REACH restriction and authorisation

Practical experience of undertaking AoAs for restriction dossiers, and in particular for REACH applications for authorisation has provided a more rounded understanding of the reasons for them. These might be grouped under the following headings:

- Least-cost compliance scenario – An insight which has come out of the applications for authorisation process is that the analysis of alternatives informs directly what a firm would do if it had to stop using a substance. In authorisation, this is termed the 'non-use' scenario, and is used to estimate the benefits of authorising continued use of the substance in question. There is a clear read-across to the 'restriction scenario' – what firms would do if the use of a substance was restricted – and from there to the question of whether the restriction is justified and whether some continued use of the substance should be permitted (derogated).

  This is recognised, somewhat implicitly, in the good practice guide produced by the Restriction Task Force, 'Fit-for-purpose dossiers'.[8] In discussion undertaking restriction AoAs it is stated:

  > 'When determining the costs from substituting to an alternative (or mix of alternatives), it may be sufficient to assume the lowest cost alternative would be adopted (taking into account suitability). However, it should be considered if an approach of realistic mix of alternatives is more appropriate or the costs of other alternatives could be used in sensitivity analysis.'

  Thus, the issue of which alternatives affected firms might choose to adopt, and why, is raised in a way which is perhaps more 'behavioural' than the ECHA restriction guidance itself.

  However, the response to non-authorisation proposed by many firms has been not to adopt alternative substances or techniques, but rather to relocate company operations out of the EEA, or even to close down completely. Thus, an AoA focussed narrowly on alternative substances and techniques has been seen to be insufficient, in the context of an authorisation application, to identify the non-use scenario, and hence the costs and benefits of authorisation (and whether authorisation was justified). Rather, the scope has had to be expanded to consider 'managerial' responses to non-authorisation, such as relocation, as well as their costs.

  The effect of incorporating additional types of response to authorisation and restriction into the analysis is to reduce the estimated cost of the non-use or restriction proposal. Managerial responses such as outsourcing have also been proposed in applications for authorisation as a way of reducing the costs of substitution (e.g. the need for temporary closure while new technology is installed and tested). Thus, estimating the costs of a

[8] https://echa.europa.eu/documents/10162/17233/rtf_fit-for-purpose_dossiers_en.pdf/

restriction based solely on the costs of adopting alternatives is likely to overestimate the true costs.

Thus, a broader interpretation of the objectives of an AoA is to estimate the least-cost restriction compliance scenario – what firms will actually do if a restriction is implemented. This could involve adopting a technical alternative (e.g. a different substance) but could also mean changing business operations. These types of issues are naturally raised in a SEA, However, keeping in mind the need to identify the most likely response to a restriction should help to focus the AoA on those alternatives which are might actually be feasible for firms to adopt;

- Effectiveness and proportionality – This is as already described in the ECHA guidance. The AoA here identifies costs of alternatives for firms, and hence of substitution for stakeholders and society as a whole, and whether substitution would result in a reduction in risks. It therefore considers whether substitution is justified as the individual firm level and whether the restriction is justified overall. In combination with an understanding of the likely 'non-use scenario', the focus here will be more on those alternatives which are most likely to be adopted in the event of a restriction, and whether that substitution is beneficial and proportionate from a societal point of view;

- Derogations – This too replicates the objective in the ECHA guidance. Here, the AoA seeks to identify where the costs of adopting alternatives are less than benefits and hence derogations might be justified, and to identify the costs of transition and hence what transitionary arrangements might be justified;

- Regrettable substitution – Related to the derogation issue, the AoA might identify one or more alternatives to which a major segment of industry would move to in the non-use scenario, but which would not generate a reduction in human health and/or environmental risks. This might be used to extend the scope of the restriction to include these alternatives and prevent such 'regrettable substitution' (although it would remain to be demonstrated that the benefits of this broader restriction would be greater than (proportionate to) the cost of whatever the 'new' non-use scenario would be);

- Research and communication – One of the stated objectives of the AoA in applications for authorisation is to facilitate the public consultation on alternatives. The AoA sets out what the applicant knows about alternatives, and the public consultation invites external actors to provide corrections or additional information. Thus, the authorisation AoA has the dual role of scrutiny – ensuring that the applicant has done a thorough job of searching for alternatives – and research – seeking information to fill genuine gaps in knowledge and understanding. The AoA in a restriction dossier can serve a similar function, highlighting evidence gaps and uncertainties and inviting contributions from the public to resolve them. Plus, it can set out the evidence supporting a restriction and the justification for intervention, and demonstrate that options have been properly considered and scrutinised. Finally, a restriction AoA has the role of communicating the information collected by the DS, and the associated justification, scope *etc* to RAC and SEAC as part of the opinion-making process. This highlights the difference between the Annex XV dossier, which is submitted by the DS to the ECHA scientific committees, and the restriction background

document, which is the committees' adaptation of the Annex XV dossier developed to support their opinion on the restriction.

This interpretation of the objectives of a restriction AoA clearly widens the scope of the analysis and blurs the boundaries between the AoA and other parts of the Annex XV dossier. It is not the intention here to 'reinvent' the restriction AoA/SEA methodology or produce new guidance. However, it is useful to highlight these links because it might change, and in some ways simplify, how AoAs are undertaken in practice. The following section considers what an AoA might need if it is to meet the various objectives outlined above.

What features should a restriction AoA have to achieve these objectives?

The various objectives of a restriction AoA, discussed in the previous section, might be summarised as to estimate the least-cost compliance scenario, to encourage effectiveness and proportionality, to refine the scope of the restriction by identifying derogations and regrettable substitutions, and to aid research and communication. The next question is what the AoA might need to look like to achieve those objectives. A number of suggestions are discussed here.

First (not necessarily in order of importance or logic), the AoA needs to set out a clear statement of the different uses of the substance and its function in those uses. This would help to identify alternatives to the substance in those uses, whose comparable performance should also be set out so that the potential for substitution – and the implications of performance deficiencies, and the costs of mitigating them – can be assessed.

When assessing the suitability of alternatives, DSs should keep in mind the need to predict what the response of industry would be to any particular restriction. Firms will not necessarily adopt one of the identified technical alternatives, but might instead (e.g.) change their processes, relocate the businesses, or close down. Recognising these additional compliance options should generate a more accurate (and lower) estimate of the costs of the restriction, and simplify the analysis by excluding technical options which are clearly commercially unviable.

The AoA should identify the key information sources which drive the analysis, as well as gaps and weaknesses in available information. This will help to signpost requirements and priorities for new information. In this respect, it is helpful to present data on the relative scope of uses – volumes and values of production, volume of substance use *etc* – so that the most important segments can be identified and prioritised for examination.

Finally, there should be a clear structure and presentation of the information and analysis in the AoA, to aid the understanding of the evidence and scrutiny of the findings.

The constraints and hurdles to producing the ideal restriction AoA

DSs face various constraints and hurdles when undertaking restriction AoAs which might affect their ability to produce one with the features outlined in the previous section. Some of these will be considered here, in comparison with the equivalent situation with authorisation AoAs.

First, Annex XV dossiers are compiled and submitted by ECHA or Member State Competent Authorities. They are therefore almost entirely dependent on third parties – particularly, individual firms and industry groups – for information on existing processes and alternatives. Industry has had little incentive to provide information in a timely manner, since the implications have tended to be delays to the regulatory process and weakened regulatory standards.

With authorisation, the applicant is required to present information on its own technology and substitution possibilities in order to obtain what is effectively a time-limited derogation from a ban on the use of a substance. If the information is deemed inadequate by the scientific committees or the Commission, the risk for applicants is that their application will be rejected and they will not get their derogation.

Although this has rarely happened so far, it seems the risk of rejection (or a shorter review period) has been sufficient for most applicants to take the process seriously and provide meaningful information on alternatives (as well as other evidence to support their derogation request). Latterly, there seems to have been something of a change in the assumed position regarding restrictions, whereby the burden of proof of whether a restriction is technically and economically feasible or not has shifted somewhat to industry, to the extent that, if they do not provide any information to the contrary, the regulator will assume that it would not be problematic for industry to comply with the restriction. This has increased the incentive of firms and industry bodies to input information into the process if a restriction would be costly for them. Nevertheless, it still remains the case that, compared with the authorisation process, Annex XV DSs face a relative information deficit over industry processes and alternatives, and this will always make undertaking an AoA a challenging exercise.

Moreover, restriction proposals tend to have a much wider scope than most authorisation applications, which in the main have focused on a small number of uses (even a single use) by a small number of companies (most often a single one). Restrictions are by definition Union-wide in scope, covering potentially many sectors, many uses and many firms. Even for restrictions of relatively limited scope, the number of affected companies and products can be significant – the restriction proposal on the use of D4 and D5 in wash-off PCPs was thought to affect thousands of products, most using small amounts (1% b/w) of substance and others high (75%) concentrations. The information requirements for a restrictions are therefore not only ‘external’ to the DS, but also almost certainly much greater than for an authorisation. In addition, as happened with the D4-D5 dossier, they can often relate to technologies and products which are proprietary and hence subject to confidentiality barriers.

Finally there are some basic logistical issues which can make compiling the ‘ideal’ restriction AoA difficult. The wide scope and extensive data requirements just mentioned mean a restriction AoA can itself be an extensive and complex piece of work, at least in principle. But a limited availability of resources to compile dossiers, and a desire to communicate evidence and justification clearly to the scientific communities and the general public can conflict with the need to reflect this complexity adequately. Even the requirement to follow the prescribed Annex XV templates might impinge upon the ability to present the AoA in the best way (an issue discussed further below).

Having considered the different objectives, features and difficulties associated with undertaking restriction AoAs, the remainder of this paper considers each of the selected restrictions in turn, and assesses their AoAs against these various factors. The paper concludes with some suggestions.

How do the selected restriction AoAs compare with the proposed model?

Recognising the constraints faced by DSs when compiling AoAs, the next task is to review the selected examples to see how they compare with the 'model' AoA sketched out previously. The dossiers are dealt with in chronological order, which serves to illustrate how practice has changed over time, as guidance has changed and, potentially, how the understanding of the role of the AoA (and restriction dossier generally) has changed. The variation in the scope and nature of the dossiers is such that a formal assessment of each against the 'model' is not really feasible. Instead, the intention is to describe how the AoA information was presented in each dossier and how the various 'model' criteria were covered. It is hoped this approach gives a sense of the extent to which the dossier was successful in demonstrating a 'successful' AoA.

1. *The use of bisphenol A in thermal paper*

This restriction proposal was submitted by the French CA, ANSES, in May 2014. It proposed to ban the use of BPA in thermal paper in concentrations equal to or greater than 0.02% by weight. Thermal paper is paper which is covered in at least one chemical layer containing dye which is 'activated' when heated. It is used for tickets, till receipts, adhesive labels and so on. BPA was widely used as a dye 'developer' in thermal paper in the EU, but was linked with endocrine disrupting effects in women, who might get exposed if they had jobs handling thermal paper, such as shop assistants.

The Annex XV dossier follows the template in place at the time of compilation. As a result, the type of information identified above as being relevant to achieving the objectives of the AoA is presented throughout the dossier. The first AoA-relevant information is in Section B ('Information on hazard and risk'), and particularly Section B2.2 on uses of BPA, which includes a table listing 2½ pages' worth of different uses of BPA, as well as another which explains how the use of BPA in thermal paper accounts for 0.16% of the total annual use of BPA in the EU. It is page 39 of the dossier (Section B2.4.1. 'BPA-containing thermal paper: tonnage and applications') where the first mention of the technical reasons for the use of BPA is made:

> 'BPA still dominates the market of dye developers in thermal paper due to its efficacy, availability, and low cost. Indeed, BPA is considered as efficient, available and cheap. BPA is deemed very performing in particular for thermal eco-paper used for points-of-sales tickets and receipts which have to be printed fast and do not require any particular security features or longevity characteristic.'

This is also where price information on BPA is first provided. In the following section ('Concentration of BPA in thermal paper'), it is reported that a stakeholder consultation suggested that BPA concentrations are optimised and fully adjusted to:

> 'The functional characteristics targeted for each specific end-use (printing durability, speed, printing device, etc.). As a result, the BPA content currently present in thermal paper can be considered as the content which guarantees the technical efficiency of the thermal paper.'

The AoA proper is found in Section C, where it is described how various reports were reviewed to obtain a long list of 30 potential substitutes for BPA in thermal paper, subsequently narrowed down to 10 because reports indicated they were poor performing or were not knowingly used anywhere. Alternative printing techniques are also considered. However, no formal description of the performance of thermal paper or of BPA as a dye developer is provided which would allow a comparison with these alternative techniques and substances. For the alternative substances, physicochemical properties are listed but not explained or assessed. For bisphenol S (BPS, subsequently described as the most likely replaced for BPA), results of toxicity studies are described extensively, but technical and economic feasibility is covered in two short paragraphs, where it is described that BPS is used in Japan and the US, a Japanese representative described that the quality of products was not as good as with BPA, and some price data are provided with the conclusion that BPS is therefore 'higher price' than BPA.

For other substances, physicochemical properties are again presented but not compared or assessed, toxicity information is presented where available, and technical and economic feasibility is assessed in a few sentences, such as:

> 'It is unknown whether BPF is actually used in thermal paper but there is no indication that it is not. Given that BPF has similar properties to BPA, it can be considered as (at least) theoretically usable as a dye developer in thermal paper and thus technically feasible. As regards to its economic feasibility, it is impossible to conclude since no data could be found on its price' and,

> 'Given that 1,2-diphenoxyethane seems to be used in thermal paper, it can be deemed as technically feasible. As regards to its economic feasibility, it is impossible to conclude since no data could be found on its price.'

Thus, the AoA presents a lot of information on some aspects of the alternative substances, particularly health and environmental toxicity and risks, but little or no information on others, such as technical and economic feasibility. Even if an alternative is described thus:

> 'It is unknown whether TGSA is actually used in thermal paper, so it is difficult to conclude on its technical feasibility. Likewise, as regards its economic feasibility, it is impossible to conclude since no data could be found on its price,'

this does not prevent the DS presenting two pages of hazard information. Even where an alternative is assessed relatively positively from a technical feasibility perspective, the lack of a formal classification of uses of thermal paper mean it is difficult to assess just how feasible substitution would be. For instance, the following is provided on one substance:

> 'ETPA confirmed that some special applications of thermal papers required the use of alternatives such as D8 which is currently used in applications requiring highly sensitive paper (e.g. mobile printers needing less energy when the paper is more sensitive, queuing ticket printers...)'

but no further information is provided. Another alternative is assigned a '++' score for technical feasibility (compared with '+++' for BPS), even though no actual information on its use in thermal paper was obtained from the stakeholder consultation.

Although anecdotal evidence was provided of the technical inferiority of BPS and other alternatives to BPA in particular uses, no derogations from the scope of the restriction were proposed.

By way of summary, it is important to bear in mind that the BPA dossier was a relatively early example which could be said to reflect the understanding of the role of the AoA at the time. The dossier generally includes a lot of information which does not contribute to the justification of the restriction scope (e.g. information on other uses of BPA) or findings (e.g. hazard information on alternatives for which little or no evidence of their technical or economic feasibility exists). It seems from the information provided that BPS was clearly the obvious choice of alternative, since this was the substance identified as being mostly used in those countries where BPA had already been banned. However, rather than to use this to 'short cut' the AoA and focus more on areas where it was reported that BPS was less effective – and hence where derogations might be justified – no more detailed breakdown of uses and alternatives is undertaken. The dossier also did not consider whether EU-based manufacturers might simply choose to import BPS-based thermal paper from countries which were already manufacturing it, rather than incur the costs of switching over their own EU operations.

2. *The use of D4 and D5 in wash-off personal care products (PCPs)*

This restriction proposal was submitted by the UK CA, HSE, in June 2015. It proposed to ban the use of the siloxanes D4 and D5 in concentrations equal to or greater than 0.1% by weight in PCPs which are designed to be washed off immediately in normal use. The introduction to the proposal explains:

> 'The relative contributions of the different applications [of D4 and D5] to the total EU emissions were evaluated, so that risk management could be focussed on those applications that lead to the greatest risk to surface waters. Wash-off PCPs account for the majority of the D5 emitted to waste water at this scale.'

Thus, a difference can be seen compared with the BPA dossier, where comparative use information did not contribute to the justification of the scope of the restriction, and hence was essentially superfluous. Here, this information was specifically used to identify the use of the substance which had the highest risk impact pathway, and hence directly defined the scope of the restriction.

D4 was further included within the scope to prevent substitution of D5 with D4. Uses of the substances covered by the restriction are first mentioned in Section B2.2 ('Uses'), as hair-conditioning agents, skin-conditioning agents (emollients), and solvents in PCPs such as shower gels, bath oils and shampoo. The dossier follows the Annex XV template in existence at the time, but also includes an annex with a more extensive presentation of information on alternatives (as

well as a confidential annex on economic impacts). Thus, although the extensive 'iteration' towards the restriction scope meant that much AoA-relevant information was distributed throughout the dossier, this disadvantage was addressed somewhat by having a dedicated location where all such information could be stated, even if this meant some repetition.

Much of the uses and alternatives information presented in the dossier was collected through a survey administered for Cosmetics Europe. Volumes are presented in the section on environmental exposures, since use volumes determine releases. It is here also that it is first suggested that considerable substitution of D5 might already have occurred, since only 2% of the 2,500 new 'rinse-off' shampoo and conditioner products released onto the EU market in the year to March 2013 contained D5.

As per the Annex XV template, the AoA immediately follows the section on releases and risks, before the economic context of the uses of the substances has been established. An industry report is cited which specifies the preference for the use of D5 in PCPs as follows:

- acts as a hydrophobic solvent/dispersant for silicone polymers and other PCP ingredients,
- has high skin compatibility, and is tasteless, odourless and colourless,
- evaporates very easily from hair and skin (in a matter of hours at room temperature, or more quickly with hair dryers),
- has low surface tension, allowing it to spread rapidly on skin and hair (and thereby deliver other PCP ingredients in a uniform manner), and
- has low chemical reactivity in acidic or aqueous products, can withstand processing temperatures up to 80 ºC, and provides a product shelf-life of up to three years.

However, the Cosmetics Europe survey is cited as support for the statistics that products containing D4 and/or D5 only account for about 36% of PCPs in terms of EU market value, and only around 4% of the D4/D5 used in this sector is actually used in rinse-off PCPs. Moreover, the D4/D5 concentration in wash-off hair care products is said to range from 0.1 to 75% w/w (the higher value for a small number of products; the median being 2% w/w). As the report states:

> 'It is clear that no major wash-off PCP group (shampoos, conditioners, shaving products, etc.) is completely dependent on their presence [of D4/D5]. It also means that there are many wash-off PCPs available that can deliver the intended function (e.g. hair washing) without containing D4 or D5.

Ultimately, although the AoA sets out some fairly generic reasons why D4 and D5 might be used in wash-off PCPs, it does not establish what a product containing D4/D5 will have against a product which does not contain them, or why so few products actually use D4/D5. As the dossier recognises, individual formulations might be subject to trade secrecy, which makes it difficult to analyse alternative substances in terms of their technical and economic feasibility. Unfortunately, the Cosmetics Europe survey considered the technical feasibility of alternatives almost entirely in relation to leave-on PCPs.

As a result, the separate annex on alternatives is not particularly useful in understanding what the non-use scenario would be or what costs it would have. Rather, and reasonably – in light of the large number of products already available which do not use D4 or D5 – the economic assessment focuses more on how much it would cost, and how long it might take, to reformulate products, rather than to replace one ingredient specifically with another. The resulting cost is then compared

against a value of D4/D5 products obtained from a dedicated stated preference survey (although there must be some question mark over how meaningful such a value could be if it is not particularly possible to say what it is which D4 and D5 provide to PCPs).

Ultimately, this case is faced with a general lack of alternatives information, made complicated by trade secrecy in the area, but also seemingly with a simple absence of primary research. It is clear most products do not use D4 or D5, but not exactly clear why those that use them do use them. As such, the AoA undertaken is less important, and the reformulation approach adopted for costing is a reasonable one. However, it is difficult to avoid mentioning the question of whether the AoA missed the bigger point, which is do consumers need a substitute for D4/D5 at all? If not, it would be simpler and cheaper to avoid reformulating the products which use D4 and D5 and just to remove them from the market. If this was the case, the costs of the restriction would simply have been the loss in 'consumer surplus' associated with use of D4/D5-based products, which could be estimated simply from product sales figures and some assumptions about demand elasticity. This would still have been a useful exercise as a check on the costs estimated via the route which was actually adopted, since the value of consumer surplus is an upper bound on the longer-term costs of the restriction.

No particular derogations were considered from the proposed restriction. The initial scope was selected through a consideration of the significance of different sources of D4 and D5, for instance between leave-on and wash-off products – leave-on products were excluded from the scope of this proposal due to limits on exposure through this route, which could be considered a derogation, but not one based on AoA information.

3. *The use of four phthalates in consumer articles*

This restriction proposal was submitted by ECHA in April 2016. It was, therefore, the first of the proposals considered in this note to follow the revised Annex XV template issued in October 2015. Thus the dossier starts with a section entitled 'The Problem Identified,' which focuses on hazard and exposure information. Much of the information about uses is first found here under exposure assessment, although this is repeated later in the 'Baseline' section, which clearly states the scope of the proposal. The four phthalates in question, DEHP, DBP, DIBP and BBP, are used as plasticisers in a wide range of articles, and the restriction focuses on those articles which present risks to human health via the critical exposure routes: oral (due to mouthing) and dermal or mucous membrane in an indoor or outdoor environment; and, oral (due to ingestion of dust) or inhalation in an indoor environment. Although the new template makes this presentation clearer than in the previous two dossiers, it still serves to illustrate that it is difficult to see an AoA as a 'standalone' undertaking.

The revised template greatly shortens the main Annex XV dossier, and puts much of the detailed information in annexes. In the 4 Phthalates dossier, alternatives and substitution are covered in Section 2.3.2 ('Transitioning to alternatives'), where the likely substitutes are listed, and their technical and economic feasibility, availability and risk implications are summarised. In this case, industry engagement seemed to be forthcoming, perhaps due to the fact that very little manufacturing using the four phthalates was thought to remain in the EU. EU manufacturers had almost completely (97%) transitioned to alternatives already, and hence the main target of the restriction would be important articles. To the extent that these might be

cheaper competitors to products manufactured in the EU, EU producers would have an incentive to provide information if they think this might increase the chances of a restriction.

Annex D.2. ('Alternatives') included a clear statement of the technical properties of the four phthalates which explains their use in different product types. Technical feasibility selection criteria were set out against which alternatives were to be compared. This exercise was assisted by the fact that a large-scale application for authorisation to use phthalates was submitted in 2013, which the DS was able to draw on for alternatives information. This demonstrates the different incentives present in the authorisation and restriction processes for industry to disclose information. ECHA had also previously commissioned a consultancy study on the availability and cost of phthalates alternatives, in preparation for the 4 Phthalates dossier.

A previous Annex XV dossier had also been compiled on the four phthalates but had not been supported by the ECHA Scientific Committees due to its being considered too broad in scope. The work undertaken for this dossier was used to identify the most likely alternatives (based on previous market experience) for each of the four phthalates in the various uses to which they are put.

Only quite generalised information on substitution costs is presented in the AoA itself. Rather, costs are calculated later on in Annex D for various scenarios of economic impact. It is possible that non-EU producers of plastic articles meant for the EU market could have simply stopped supplying the EU rather than engage in costly substitution activities. However, the conclusion of the cost assessment was that the alternatives were of largely similar cost, and hence this 'managerial' response was unlikely to be relevant (although the possibility does not appear to have been considered explicitly).

Derogations from the restriction were considered in some detail in Annex D. Derogations were identified for articles which it was considered did not represent a significant source of exposure in normal use. As such, therefore, the AoA did not play a direct role in this process. The scope of the restriction was probably too wide to be able to identify those uses for which compliance would be extremely difficult or costly. Even for manufacturers outside the EU, these might still be considered eligible for derogation because of the potential impact on EU consumers. However, one of the roles of the public consultation is to enable industry sectors to signal their need for a derogation, so this omission might not be considered unreasonable.

4. *The use of lead in PVC articles*

This Annex XV dossier was submitted by ECHA in December 2016, and proposed to ban the presence of lead in PVC articles if the concentration of lead (expressed as metal) was equal to or greater than 0.1% by weight of the PVC material. As with the 4 Phthalates dossier, this proposal followed the updated Annex XV template, with a shorter main report backed by more detailed annexes. However, even though the first section of the dossier proper is entitled 'Identity of the substances and physical and chemical properties', the very first lines are:

> 'This restriction proposal concerns lead compounds used as PVC stabilisers in a variety of applications (window profiles, cable insulation, pipes and flooring etc.). The stabilisers allow the PVC to endure longer fabrication (heating) time and protect against photo-degradation, thereby prolonging the service life.'

This perhaps illustrates a recognition of the value of stating up-front what the intention and scope of the restriction proposal are, rather than starting first with an assessment of hazard and risk. Although clearly this latter is the ultimate justification for action, it is not necessarily the best place to start when communicating the justification for a specific restriction proposal. The updated template, whilst clearly an improvement on the previous version, still seems to present something of a 'record' of the restriction proposal process, which does not necessarily best communicate the outcome of that process.

Similar to the 4 Phthalates case, EU industry had already reduced its use of lead in articles, through a voluntary commitment to phase out the use of lead in PVC by the end of 2015. However, not all users of lead stabilisers were part of this scheme, so that some limited remaining uses were reported in the public consultation. *In vitro* diagnostic medical equipment and PVC silica separators in batteries were two uses mentioned specifically, and it is possible (although not apparently considered) that manufacturers in these sectors chose not to join the scheme because they faced higher substitution costs than others. In addition, the lead concentration ranges for the different applications were deemed to be still potentially applicable for imported PVC articles, since these are produced mainly in Asian countries where lead compounds were still widely used as PVC stabilisers. Thus, the principal impacts of the proposal were expected to be on EU consumers of imported articles.

A number of possible alternatives were considered in the AoA but rejected because they had already been restricted in the EU or were deemed technically infeasible. The AoA was clearly assisted by existing industry efforts to substitute lead, which indicated that calcium-based stabilisers had generally been the substitute of choice. This was supported by a comparison of the performance characteristics of lead and calcium stabilisers. No other alternative was considered a likely choice. Economic feasibility was assessed via an example calculation of the cost implications of using calcium stabilisers in PVC window profiles – although it is not clear this was the most representative use for such an assessment. Based on this calculation, and a more general one based on the relative costs and 'dosage' of lead and calcium stabilisers, the conclusion was that the restriction would not have a significant cost impact. As a result, 'managerial' responses to the restriction were less likely to be relevant.

A number of derogations from the restriction were analysed, but these were based on direct communications with stakeholders rather than the AoA. The very wide scope of uses covered by the restriction did not allow for an identification of very specific uses and their alternatives, and hence potential problems with substitution were alerted through the public consultation.

5. *The use of lead in gunshot pellets*

This Annex XV dossier was submitted by ECHA in April 2017, making it the most recent of the dossiers considered in this note. As such, it demonstrates further development of 'thinking' regarding the best dossier structure. The summary provides a self-contained and non-technical explanation of the proposals, its context, objectives and impacts, which acts as a useful 'signpost' for the rest of the document. In addition, the document proper starts with several sections outlining the nature of the general problem (impacts on wildfowl of using lead gunshot pellets over wetlands), the regulatory context, the use of lead-based ammunition, and the nature of wetlands in Europe, *before* continuing with the 'standard' template and discussing the hazards and risks associated with lead. Within the shorter Annex XV dossier format, this helps

to unify the document and make it easier to navigate, because the reader is 'forewarned' about the overall content without needing to follow the whole thread from the beginning.

The main dossier explained how lead-free shot has been available for several decades, how it has different price and performance characteristics from lead shot, and how one of the major costs of switching to it is from reproofing shotguns to make them compatible. It also reviewed the different approaches to regulation adopted among Member States, showing that several had already banned lead shot to different degrees. It also makes the unusual step of providing a response to various claims made about non-lead cartridges which were encountered during the Annex XV process, either in popular media, discussion between hunters in internet fora and other sources. This indicates how the Annex XV dossier was being used at least partly as a 'communications' vehicle to stakeholders, perhaps in recognition of the controversy surrounding the proposal.

This might also explain why the dossier goes into considerable detail (in Annex E.3.1.2. on technical feasible) on the comparative performance of lead and lead-free (particularly steel as the most likely alternative) shot, including the mechanics of shooting, kill efficiency and so on. There is a similarly detailed consideration of the technical implications for shotguns. In comparison, the review of price differences across different types of shotgun cartridge is less persuasive – a listing of prices found online for lead and lead-free cartridges in different countries in the EU serves to demonstrate how much price variation there is, without offering much explanation as to why.

The impact of the restriction was seen to depend on how an individual hunter would respond to it – some might be able to switch directly to steel cartridges, some might need to have their gun proofed first, and others might need to retire their gun prematurely and replace it with a steel-compatible model. All hunters were assumed to adopt one of these strategies – no consideration appears to have been given to the possibility some hunters might simply stop hunting over wetlands (although the issue of non-compliance – whereby hunters respond simply by continuing to use lead shot over wetlands – is briefly discussed).

No specific consideration appears to have been given to possible derogations from the restriction. This might be because the restriction does not as such ban the use of lead shot or any particular type of gun, but only their use in particular locations (over wetlands). Any derogation could therefore have provided an incentive to hunters to use derogated equipment even if they were able to use lead-free shot at relatively low additional cost.

Concluding remarks

By their very nature, restriction dossiers are complex and complicated studies, with a large number of different objectives. An authorisation application takes an existing ban of a defined Substance of Very High Concern and considers the implications of that ban for a limited group of identified user and uses. Restriction dossiers, however, must in principle:

- identify a substance of concern;
- explain which uses and associated impact pathways are the sources of that concern;
- identify what the alternatives for those uses might be; and

- calculate what the costs and benefits would be of restricting one or more of those uses,

all with a view to iterating towards and finally defining the scope of a restriction (or, indeed, some other risk management option).

An authorisation application might do its job in four separate reports (the chemical safety report, analysis of alternatives, socio-economic analysis, substitution plan), but a restriction dossier in principle covers everything in a single document.

It is therefore unsurprising that the latest version of the Annex XV dossier template encourages DSs to shorten the main body of the dossier and present more concentrated analyses in supporting annexes – the lead in shotgun pellets dossier considered above benefitted from this more targeted approach. Similarly, the dossier covering lead in PVC articles was clearly helped by being a development of an earlier dossier which RAC and SEAC had rejected for being too broadly scoped. The dossier on phthalates in articles was also able to draw on earlier applications for authorisation submitted by manufacturers of plasticisers. The implication is that a 'collection' of more focused documents is better at presenting the evidence for a restriction than a single, large 'tome' which documents the development of proposal 'from start to finish'. A more iterative approach to developing the final dossier would also help to distil the main messages and communicate the analysis and evidence more clearly.

Nevertheless, recording the development of a restriction proposal will always be a complex matter, especially given its iterative nature and the multiple objectives of a restriction dossier. However, in all but one of the dossiers considered in this review, the analysis was, or could have been, simplified considerably because there was a reasonably clear 'non-use scenario' – the alternative to which most uses/users would switch if they were unable to use the restricted substance. Short-cutting the AoA in this way would save time and allow more attention to be given to those uses for which there might be no commercially viable alternative – and hence where a derogation might be justified – or to the possibility that the hazard and risk characteristics of the alternative might make it a 'regrettable substitution'.

Of course, if there is no obvious non-use scenario, no such short cut might be possible. But it is worth noting that, in the one dossier considered here which did not appear to have a ready alternative (D4/D5), it was not unequivocally demonstrated that a direct alternative was actually necessary at all. This observation arose in part because of the lack of a clear explanation of the functional value of the substances in consumer products, especially given the very small proportion of the market apparently accounted for by them. This also might have suggested a simpler approach to the estimation of the costs of the restriction.

Ultimately, however, it is not clear that any of the dossiers considered in this review came up with what might be considered the 'wrong' overall conclusion, in the sense that the costs of the restriction outweighed the benefits. If costs could have been better estimated, it seems likely they would have been lower, and the estimates that were generated were exaggerated, rather than downplayed, and hence could be regarded as 'cautious' to the restriction decision. This too reflects in part the fact that all (but one) of the restrictions related to 'easy' substitutions towards clear alternatives, and this will not always be true of more difficult cases.

Where there is no clear alternative of similar performance and cost, it is important to consider whether 'managerial' responses in the non-use scenario (such as relocation or shut-down) are more likely to be adopted than some more costly and technically infeasible substitute. This is to avoid a restriction having 'unintended consequences' on affected sectors and the wider economy.

This will not necessarily be relevant to all restrictions, as the cases considered in this paper indicate. One (BPA in thermal paper) had a reasonably clear alternative substance, based on experience in non-EU countries which had already banned BPA. For two (4 phthalates and lead in PVC), the proposed restriction would only apply to imported articles as the substances had already been restricted in manufacturing in the EU, but there could have been a possibility that non-EU manufacturers would simply stop supplying EU markets rather than face the costs of switching. Similarly, given the apparently small market for products containing D4 and D5, manufacturers might simply have dropped those products from their portfolios, rather than face the costs of reformulating them. For lead in gunshot, there was an apparently clear alternative substance (steel), but given that this was a restriction on behaviour as much as on lead (that is, the restriction did not propose to ban the use of lead shot in cartridges, only the use of such cartridges over wetlands), gun users might simply have opted to stop shooting over wetlands, (although evidence of similar bans in individual MSs did not suggest this would be widespread) or to ignore the restriction (for which there was more evidence).

To a large extent it will not be possible to assess managerial responses without proper input from firms and business groups and, where relevant, consumers. One of the lessons of the authorisation process is that firms are generally the best judge of their likely response to the requirement to stop using a substance. The public consultation on alternatives has rarely thrown up suggestions of alternatives which might be suitable substitutes for authorisation applicants but which had not previously been considered (as one might hope if the authorisation process is working correctly). There are resources available – for example, https://www.subsportplus.eu/subsportplus/EN/Home/Home_node.html – which aim to provide information on alternatives to those seeking to substitute, but they can only provide a starting point, and all such information needs to be assessed by those with knowledge of the technological and commercial context of any particular business. DSs should not expect to be able to tell businesses which alternatives they should adopt, but should instead try to incentivise them to engage in the process and input their knowledge and expertise into the restriction process (which DSs should in turn assess from an appropriate 'scrutineer's perspective'). Presenting evidence and analysis with a clear and understandable structure will undoubtedly help in this regard – in this review, the difference between the dossiers was not so much in terms of the quality of the information generated but in the way it was laid out, and how easily the information (and lack of it) could be assimilated and understood.