

# CLP ANNEX VIII WORKABILITY STUDY

## Written Response to Study Workshop

04 March 2019

A.I.S.E. welcomes publication of the draft interim workability study report and the preliminary findings on Annex VIII of the Classification Labelling and Packaging Regulation (CLP).

We note that multiple industry sectors have identified very similar workability issues with Annex VIII. This is despite these different sectors operating in different ways to formulate their respective products. The non-industry specific nature of these workability issues supports the need for inclusive solutions to address the workability of CLP Annex VIII.

Following the recent workability study workshop on 13 February 2019, A.I.S.E. has sought to quantify the economic impact related to the implementation of Annex VIII CLP if solutions to the highlighted workability issues are not found. The impact is significant and has the potential to obliterate the costs savings identified in the 2014 Commission costs and benefits analysis<sup>1</sup> on the Annex VIII CLP proposal. It should also be mentioned that the Detergents and maintenance products sector is already subject to a disproportionate pressure in terms of costs for administrative burden (See 2016 Commission Cumulative Costs assessment for the chemical industry).

If unresolved, the workability issues posed by Annex VIII are expected to necessitate:

- multi-million-euro capital expenditure (Appendix 1)
- an unfeasible increase in plant footprint (Appendix 1)
- significant ongoing resourcing requirements (Appendix 2)

Regardless of a company's size, these outcomes are not viable. It is therefore essential that mutually agreeable solutions are found and implemented prior to the applicability of Annex VIII.

A.I.S.E. believes that it is possible to mitigate the economic impact of Annex VIII, without detriment to the activities of poison centres or appointed bodies, if non-sector specific solutions to the following issues can be found:

- inherent product variation of raw materials
- applicability of group submissions

A.I.S.E., in conjunction with our colleagues in other industries have already provided thought starters on potential solutions to the highlighted workability issues (Appendix 3 and Appendix 4).

A.I.S.E. believes that these documents illustrate that constructive and sustainable change can be achieved within the existing framework of Annex VIII. We hope that these documents serve as a starting point on the way to achieving inclusive change that works for all stakeholders.

<sup>1</sup> <http://ec.europa.eu/DocsRoom/documents/14006/attachments/1/translations>

## Appendix 1 – Preliminary assessment of the economic impact of product variation under Annex VIII

As in other sectors of the chemical industry, the Detergents sector relies heavily on multiple suppliers of the same (or technically comparable) raw materials. Despite being sourced from different supply chains, technically equivalent raw materials are stored in the same storage silos prior to use (Figure 1).

As storage silos are never allowed to run dry/be 100 % empty, these technically identical raw materials will mix in storage. Meaning that it is impossible to know the exact composition of the mixture and comply with CLP Annex VIII as currently written. In other words, in order to get the exact composition for each production batch, industry will be forced to expand its raw material storage capacity on a supply chain basis (Figure 2).

Conservatively, an additional two silos per mixture component could be expected, based on an industry average of three suppliers per component<sup>2</sup>. Note: business-critical raw materials typically have a larger number (typically: 5 – 15) of suppliers<sup>2</sup>.

To quantify the economic impact of this outcome, A.I.S.E. contacted a third part engineering company which specialises in chemical plant infrastructure. The following scoping values were quoted for an existing operational site:

**Cost/silo:** € 380,000 (estimated)

**Footprint/silo:** 30 m<sup>2</sup>.

An initial scoping estimate covers design, silo manufacture, installation, commissioning, instrumentation and project management. It does not include land procurement, site clearance or budgetary contingency. These values are capacity independent. Silo materials make a small contribution to the estimated cost, whilst capacity is modulated by silo height, not footprint.

Applying this estimate to a theoretical product, consisting of six components<sup>3</sup> with an average of three suppliers per raw material, storage requirements would increase from six silos to eighteen silos (six existing, twelve new). Using the unit costs quote above, this requirement translates to

**Additional Cost:** € 4,560,000 (estimated)

**Additional Footprint:** 360 m<sup>2</sup>.

It must be stressed that these costs relate to a single (theoretical and conservatively estimated) product. In practise, greater compositional and supply chain complexity can be expected for each of the > 900 detergent formulators that A.I.S.E. represents. Further when the product line per A.I.S.E. member is considered (typically: SME: ≤ 100 products, large member ≥.100 products), the potential additional cost in the detergents sector alone could range from several hundred thousand euro (small product lines) to multi-million euro (large product lines) depending on the A.I.S.E. member in question. As a matter of comparison, the costs savings identified in the 2014 Commission costs and benefits analysis<sup>4</sup> on CLP Annex VIII proposed a saving of 550 million euro per year; across all sectors. It should be evident that the expected costs of additional storage would obliterate the proposed cost benefits associated with the introduction of CLP Annex VIII and that in its current form CLP Annex VIII does not provide a proportionate and workable solution when it comes to product variation.

<sup>2</sup> As per Detergent sector Annex VIII workability study contribution (Question Number: B8).

<sup>3</sup> As per Detergent sector Annex VIII workability study contribution (Question Number: B9).

<sup>4</sup> <http://ec.europa.eu/DocsRoom/documents/14006/attachments/1/translations>

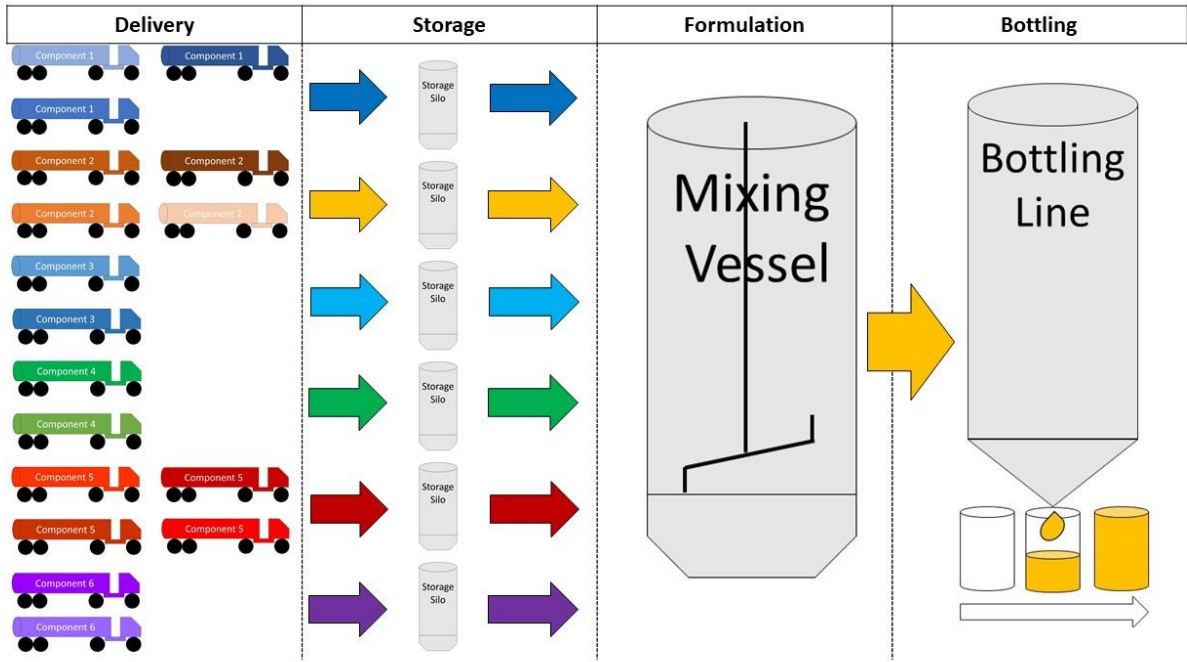


Figure 1: Raw material storage and use prior to CLP Annex VIII

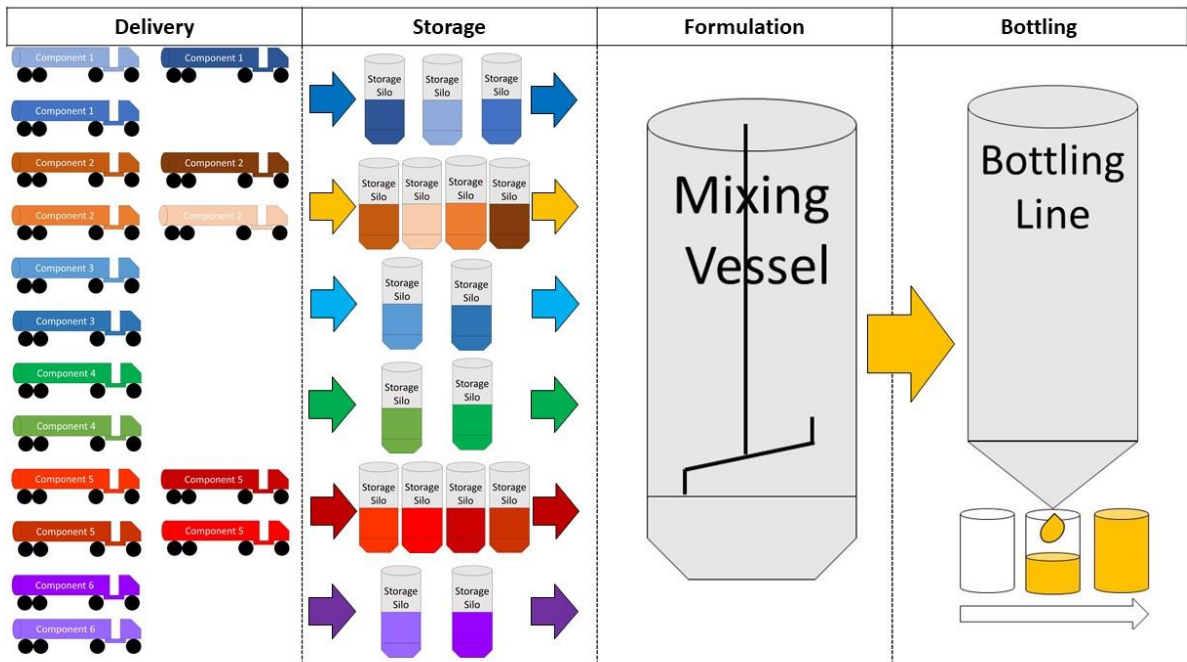


Figure 2: Raw material storage and according to CLP Annex VIII



## Appendix 2 – Economic Impact of Group Submission Under an Unamended Annex VIII

The Detergents industry, as for other sectors, will be subject to an ongoing burden to maintain compliance with Annex VIII as currently written. The limited applicability of group submissions, in part due to the restrictions on generic product identifiers, is not expected to ease this burden.

A.I.S.E. interviewed an SME to try to quantify the likely operation costs under CLP Annex VIII. The SME currently produces circa 100 formulations both own brand and as private label formulator for third parties. Each year approximately 30 % of products undergoes change either brand-new formulations (approx. 20) or revision of existing formulations (approx. 10). Presently, the company allocates the following resources to regulatory affairs:

Position	Time Allocation (REACH, CLP, BPR, Transport Regulations)	Regulatory Affairs Duties:
Research and Development Manager	0.15 – 0.2 FTE	External meetings & workshops, staff briefings.
Quality Manager	0.35 FTE	Document production & quality management (SDS, transport declarations, etc),
3 <sup>rd</sup> Party Contractor	1.0 FTE (€ 39,240/annum, contractor's fees)	Hazard classification, labelling schemes, provision of SDSs in multiple languages

Under national poison controls notification requirements, the company makes circa 50 notification per year for approximately 15 (own label) formulations across 2 – 4 European Union Member States using internal resources (estimated to be 0.05 FTE).

With the first CLP Annex VIII implementation less than 12 months away, it is still extremely difficult to accurately predict the workload that will be required under Annex VIII in its current form. This is particularly acute for toll formulators due uncertainty surrounding duty holder responsibilities. Nevertheless, the SME's current working assumption is that their Annex VIII requirements will grow to at least 372 notifications for own label products, broken down as:

- 45 initial submissions – 15 “new” formulations in three Member States
- 45 submission updates – 15 “new” formulations in three Member States (updated once/year)
- 282 submission updates – 47 “existing” formulations in three Member States (updated twice/year)

**Note:** This estimate does not account for any additional notification requirements that may arise from finalised duty holder responsibilities and the SME's activities as a toll formulator.

The requirement to complete (an average of) 7.1 notifications per week means that the SME expects their reliance on 3<sup>rd</sup> part consultant(s) to increase to 2.0 – 3.0 FTE. The additional € 39,240 – 78,480/annum required to comply with CLP Annex may pose significant issues for an SME such as this as operating margins in the detergents sector are generally low for fast moving consumer goods, particularly for private label formulations.

As detergent formulations often consist of a “base formulation”, which is adjusted for colour and fragrance, a revision to the qualification requirements for generic product identifiers would significantly reduce the number of submissions that would be required per year and therefore the additional operational costs associated with CLP Annex VIII.

## Appendix 3 – Cross Sectoral Alignment Thought Starter on Regular Product Variation

### Summary:

The inherent variability of raw materials and final product was of concern for 6 sectors (Oil, Cement, Construction, Paints/Inks, Perfumes and Detergents). Across these sectors it is reported that final product variation covers:

- Components that are either substances or mixtures
- Intentional (e.g. multi-source supply chains) or unintentional (e.g. storage conditions) variation.
- Driven by upstream (e.g. MiM suppliers) or downstream (e.g. bespoke customer requirements) factors.

### Proposed Solution:

To address the concerns above, an inclusive solution is proposed. A merger of the CM-A (“Comparable MiM”) and SD-B (“Technically Equivalent Components”) solutions identified in the workability study draft interim report is proposed. Specifically:

- ***In their submission, the notifier identifies component substance(s)/mixture(s) which are subject to variation.***
- ***For these components, the notifier identifies all alternative components that may be present due to variation, creating a limit of variation. All components subject to variation and their alternatives must be reported and:***
  - ***Be identified according to Section 3, Part B of Annex VIII information requirements (as potentially amended) or using the UFI or SDS/supplier (for notified MiM’s as per Part B 3.2.2)***
  - ***Serve the same technical function within the mixture***
  - ***Carry the same health and physical hazard classification***
- ***Validity of the submission with respect to the above criteria could be determined electronically during submission (e.g. IT check via validation assistant during submission).***
- ***Following submission, appointed bodies or ECHA would be entitled (as per Part A 3.2) to review/assess the submitted limit of variation and conduct follow up if deemed appropriate.***
- ***Assuming the notifier places formulations on the market that are within the notified limits of variation, no new UFI or submission update are required.***



## Appendix 4 – Cross Sectoral Alignment Thought Starter on Generic Product Identifiers

### Summary:

The overly narrow scope of generic product identifiers is of concern for certain sectors (Paints/Inks, Construction and Soaps/Detergents). Across these sectors current criteria for generic product identifiers are too restrictive, as they:

- Prevent the use of group submissions in a majority of submissions containing a colour or fragrance mixture, due to MiM classification
- Significantly increase the complexity of submissions due to additional disclosure of MiM components regardless of concentration in the bulk final mixture
- Increase the number of (non-value added) submission updates due to extensive ingredient disclosure and low threshold for update.

### ***Proposed Solution:***

To address some of the needs of the above sectors, it is proposed that for the generic product identifiers “perfumes”, “fragrances” or “colouring agents”, the following classifications of major concern would not be permitted (original proposal covered in the costs and benefits study). Specifically:

- ***acute toxicity, Category 1, 2 or 3,***
- ***specific target organ toxicity single exposure, Category 1 or 2,***
- ***specific target organ toxicity repeated exposure, Category 1 or 2,***
- ***skin corrosion, Category 1, 1A, 1B or 1C,***
- ***serious eye damage, Category 1.***

*Note:* this alone will not solve all issues for some sectors, and additional solutions may also be needed for specific cases e.g. point-of-sale colour mixing/tinting.

