REACH
CheMI Position for the European Parliament 2nd Reading

General

The CheMI Platform supports the position taken by the European Parliament in their wish to stress the need for a level playing field for both importers and manufacturers of products (amendment 416 recital 4a new and amendment 66 art 2.2a new).

Use & Exposure categories

The CheMI Platform strongly supports the introduction of the provision of 'use and exposure categories' as proposed by both the European Council and the European Parliament. The introduction of this provision simplifies the drafting of exposure scenarios and helps to reduce the number of 'forgotten uses'. It also contributes to the reduction of administrative burden and registration cost. The combined positive effect of these provisions contributes in turn to reduce 'market withdrawal' of small volume chemicals for economic reasons. This negative consequence is felt as particularly damaging for downstream users, who have to the bear the subsequent high cost of reformulation and adaptation of production processes (amendments 434, 435, 376 and 377; articles 3 (12) (a) new, 3 (12) (b) new, 29 (c) and 3(29)(d)).

The CheMI Platform supports the European Parliament proposals to oblige manufacturers to disseminate information about the 'use and exposure categories' in annex to the MSDS (Manufacturers' Safety Data Sheet) (amendments 378 and 160 article 29(6)(2). In the paragraph below we explain why we feel that this obligation should already be included in the pre-registration phase procedure.

Pre-registration

The CheMI Platform strongly supports the inclusion of the 'intended supported uses' and the 'use and exposure categories' in the data to be provided in pre-registration, as proposed by the European Parliament in its proposed amendments for the 1st Reading (amendments 368 article 26 (1) point (da), 139 article 26(1) point (ea) new. Such a provision would be is a major contribution to the introduction of a much needed 'early warning system' for downstream users.

It would enable downstream users to check at an early stage whether their use has been identified by the manufacturer and whether he intends to support that specific use.

When the reference to a use does not appear, the downstream user has the opportunity to establish contacts with his supplier and verify the situation. If the list of 'uses intended to be supported' was simply not complete, the omission can be rectified. However, where the manufacturer does not intend to support the use in question, the downstream user can use the time available to look for alternatives. The introduction of such provisions would significantly reduce the negative impact of 'market withdrawal' and of 'non-supported uses', since it allows downstream users to plan and spread over time the resulting need for reformulation of preparations and adaptation in production processes.

The CheMI Platform strongly supports the European Parliament amendment 371 article 26(A) new, about the publication of pre-registration including minimum information on uses covered. This would contribute to the much needed transparency for downstream users.

Registration

The CheMI Platform feels that the registration requirements have been considerably improved thanks to the amendment package introduced by the European Parliament and Council after the 1st Reading. In addition to the amendments already introduced, the CheMI Platform also strongly supports the provision relating to the obligation for manufacturers and importers to notify downstream users of their intention not to register a substance a few months before the registration deadlines, as initially proposed by the European Parliament. This would represent another major contribution to the much needed 'early warning system' for downstream users, mentioned earlier (amendment 121 article 21(A) new).

The CheMI Platform also strongly supports the principle of a 'late notification' (six months after the publication of the register) of the intention of registration by someone else than the manufacturer. This would very much help downstream users to reduce downstream need for reformulation of preparations and adaptations of production processes and help to safeguard confidentiality where this is very much needed (amendment 369/rev article 26(2) and 2(a).

The CheMI Platform does support the inclusion of use and exposure categories in the information requirements for general registration purposes (amendment 380 article 9(a)(iiia)new.

Definitions

The CheMI Platform strongly supports the clarification brought to the definition of 'undesirable use'. The Platform also welcomes the proposal from the European Parliament to clearly link any unsupported uses in the registration to the risks that my rise from that use. The proposal would help to eliminate shifting of burden from chemical producers to downstream users for the registration of uses.

The introduction of the expression 'unsupported use' and the need of scientific arguments before a use can be labeled 'unsupported', helps to protect special uses of small volumes, mainly by SMEs, from negative decisions taken on the grounds of cost considerations (amendment 76 and 77 article 3 (26)).

Confidentiality

The CheMI Platform feels that confidentiality, within the supply chain, was not adequately provided for in the original Commission proposal. There is a need to protect know-how and confidential business information between all actors in the supply chain, and we feel that the European Parliament amendment 304 article 116(2) (d) is of the utmost importance in this field. It helps to protect proprietary information without endangering the objectives of REACH (amendment 304 article 116 (2) (d)).

Downstream User Obligations & support for SME's

The CheMI Platform strongly supports the Parliament proposed amendments affecting downstream user obligations. The vast majority of member companies of the industries cooperating in the CheMI Platform, are SMEs, and without the amendments from the European Parliament on this subject,, would be obliged to perform tasks for which they are not all equipped. Especially, the exemption from exposure assessment for uses under 1 t/a (amendment 436 article 13(4) very much reduces the need for downstream registrations.

The CheMI Platform would also strongly recommend that the European Parliament supports Council amendment to article 34(4) to be found in article 34(4) bis. The Council document is very much in line with the European Parliament's view, however it goes a step further in meeting specific aspects of downstream users' obligations.

The CheMI Platform supports the amendment from the Council to article 35 in order to align it with downstream user obligations as specified in article 34(4) bis (Council amendment). The Platform therefore urges the European Parliament to support the Council approach.

Authorisation

The CheMI Platform strongly disagrees with the European Parliament approach towards authorisation. (Amendments 214, 221, 232, 235 etc). This approach forces replacement of substances of very high concern, even if adequate control is in place. This leads to high cost for reformulation of preparations and adaptations of production processes.

With regard to the publication of a priority list of substances, we understand that priorities have to be established and that a list is unavoidable, and we also understand that, when such a list exists, its publication is also unavoidable.

On the other hand the practical effect of a priority list will equal to anticipate a judgement on the level of toxicity of substances appearing on the list, and their substitution will be requested by stakeholders.. The publication of a list with priority substances will cause needs for reformulation of preparations and adaptations of production processes a long time before a decision is taken on the precise level of concern about the substance. (It is reported to us that already today some customers ask for certification that products are 'in compliance with REACH' …).

In order to avoid premature, and perhaps unnecessary reformulation of preparations and adaptations of production processes, the priority list should be kept as short as possible. It should not be longer than necessary to allocate evaluation work for one coming year or perhaps two. It should not be turned into a compilation list of all substances commonly in mind for in depth evaluation, however without adequate evidence.

The procedure for compiling the priority list should take these requirements into consideration.

At the same time CheMI Platform supports the European Parliament amendment 246 article 62 including specific information to be communicated to downstream users for all substances subject to an authorisation including each use for which the authorisation is obtained.

Consumer & downstream information

The CheMI Platform strongly objects to the excessive amount of information to be provided to other downstream users and consumers, as mentioned in the proposal of the European Parliament. This proposal would force manufacturers of articles to disclose the complete formulation of their products. There is no need for this information to be provided, since, either there is no release of the substance and the consumer is not at risk, or where a risk caused by the release of substances exists, it is adequately covered by other legislation. Introducing the obligation of publicising this information, would seriously undermine the willingness to develop new products in Europe, and would undermine the competitive situation of European manufacturers vis à vis non-European manufacturers.(Amendments 29, 30 and 31; recitals 41, 42 and 43, amendments 366 and 166 EP art 31 A new § 3).

Also in their role of receivers of the proposed information, the CheMI Platform objects to this proposal. There is no need to receive twenty or thirty different safety data sheets per preparation, for each of the ingredients of a preparation purchased. The preparation should have one single safety data sheet, adequately covering the uses to be considered. Anything else would unnecessarily increase the administrative burden for downstream users.

The CheMI Platform supports the proposed obligation for distributors to communicate the information mentioned in art EP 30.1 to downstream users (Amendment 163). The CheMI Platform does not support the creation of an European 'quality mark' as proposed by the European Parliament. REACH will be a piece of legislation, and it is not appropriate to introduce a quality mark indicating that the law has been abided to; all products should be in compliance. It would also introduce practical problems. For instance, will articles containing small volume substances, that have not yet been registered according to the legal deadlines for registration, be considered in compliance with REACH? Will there be a need for a new legal institution to grant the right to use the mark? What will the administrative burden be? (Amendment 54; recital 91A new and amendment 90 art EP 6 AA new).

Research &Development

The CheMI Platform strongly supports the changes proposed by the European Parliament with regard to substances and preparations used for R&D purposes. The changes remove constraints that would otherwise have led to excessive administrative burden, postponement of product development projects and indeed a reduction in innovation especially by SMEs (amendments 74 and 983 article 3 point 22 and amendments 75 article 3 point 33).

Evaluation

The CheMI Platform supports the European Parliament amendment in article 43(A) paragraph 15 (A) new providing for the Agency to publish a list of priority substances for evaluation in its website (amendment 193 article 435 (A).

Other Issues

The CheMI Platform strongly supports the "intermediary ex post impact assessment" provision as proposed by Parliament (amendment 311 & 823, art 132A new).

The CheMI Platform supports the calculation of 'quantities per year' as an average of the last three years. This provides an adequate solution to emotional reactions and sudden stops of supply where manufacturers reach a threshold at the end of a year (amendment 78 article 3(28).

The CheMI Platform supports the clarification of distributor obligations (amendment 163 article 30(1).

The CheMI Platform supports the proposed obligation to supply information on biodegradability and logPOW to downstream users in order to enable them to make their own safety assessment. This is information normally missing from safety data sheets (amendment 321 Annex 1A § 3 point 3.3A).

The CheMI Platform supports the Council proposal to allow downstream users participation in the Substance Information Exchange Forum (Council amendment to article 26(6). The Platform urges the European Parliament to support the amendment and correct the inconsistency between the Council amendment to article 26(6) and Council article 27 (1).

The CheMI Platform does not support the EP proposal to introduce a duty to substitute. Substitution should not be mandatory and should take into account other criteria such as adequate control of risks. Consequently, the last sentence in amendment 364 article 1(3)(c) should to be deleted.

For the CheMI Platform
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