Raising standards for consumers

POSITION PAPER

ANEC reflections on the basic directions

for the future development of the EU legislative framework on Food Contact Material (FCM)

Main Author: Dr. Franz Fiala, former Chair of ANEC Sustainability WG

Contact at Secretariat: Michela Vuerich – mvu@anec.eu

ANEC is supported financially by the European Union & EFTA

Ref: ANEC-PT-2020-CEG-002

16/12/2020

European Association for the Co-ordination of Consumers Representation in Standardisation aisbl

Av. de Tervuren 32, Box 27 - B-1040 Brussels, Belgium
T: +32-2-7432470 / anec@anec.eu / www.anec.eu

SUMMARY

It has been known for a long time that the current regulatory framework for Food Contact Materials (FCM) is deficient and puts consumers at risk. Harmonised rules (particularly for plastics) are incomplete and outdated; implementing measures for most other materials are missing. So far, the Commission has done little to improve the situation. Several initiatives were started but put on hold later, such as the envisaged actions outlined in the "Roadmap" entitled "Food Contact Materials - Specific provisions for materials other than plastics – implementing measure" published in 2012; the revision of the Ceramics Directive, and the implementation of rules for printing inks. The European Parliament adopted a resolution on the implementation of the FCM Regulation in October 2016 expressing deep concern about health risks resulting from missing regulations stating that "*materials not regulated by specific EU measures can pose a risk to public health and give rise to loss of consumer trust, legal uncertainty and increased compliance costs for operators*".

When starting its reflections on regulating printing inks, the Commission expressed some sympathy for ideas presented in several publications by the recently-retired Swiss civil servant, Dr Konrad Grob, then of Kantonales Labor Zürich. At the centre of its approach, it proposed the idea to abandon the establishment of detailed provisions, including positive lists of substances allowed to be used. Instead, private accredited "designated bodies" ("commercial laboratories" and "other consultants") would endorse acceptable substances and materials which would then be compiled in a database and become de facto legal provisions. Dr Grob himself advocates an approach "*moving from legislation supporting industry towards checking self-control*" and "*as much as possible of the control should be transferred to private institutions*". We fear this suggested cure, written in the spirit of privatisation, liberalisation and deregulation, may be worse than the disease.

By contrast, we believe that the prevailing system of industry self-control in the field of food contact materials has failed and must be much reduced, whilst assessments by national authorities and EFSA - independent of industry - must be considerably reinforced. Experience has shown private certification bodies not to be "independent" necessarily - on the contrary, these bodies operate in highly competitive markets, and their commercial interests will always be in a permanent state of tension with their presumed impartiality, particularly where the margin of discretion is significant (as in the case of toxicological assessments). Some examples are given in this paper.

It also remains entirely unclear why a post market surveillance system based on numerous (diverging) risk assessments of numerous actors, including numerous private bodies and enforcement agencies, should be more efficient and lead to better results than a single risk assessment, which is done once by a single institution, prior to placing a product on the market. The proposed changes would

– if implemented - lead to less efficiency, less consistency and less consumer safety and thus constitute a "disimprovement".

The alternative approach we promote is based on the following principles:

- Radical reduction of substances and materials – drastically reducing the number of substances and materials to be assessed by introducing the measures outlined in the following bullet points.
- Elimination of substances of (high) concern in all types of FCM – automatically eliminate certain hazardous substances based on their intrinsic properties in a generic fashion (e.g. SVHCs, CMRs), or based on a case by case basis (e.g. endocrine disrupters), horizontally in all FCMs.
- Pre-market authorisation for substances and materials - not only substances used in the production but – in the long run - also final materials (including non-intentionally added substances, NIAS) must be authorised by EFSA prior to placing FCMs on the market. In general, positive lists based on existing national legislation and guidance papers shall be established following a priority programme, such as proposed by the EU Parliament (paper and board, varnishes and coatings, metals and alloys, printing inks and adhesives). For some materials, a positive list may be of limited relevance or even unnecessary (e.g. glass, ceramics). It may be sufficient in these latter cases to establish migration limits.
- Expiry date for all authorisations - an expiry date (e.g. 5 years) must be set for approved substances and materials, in line with the provisions for materials in contact with drinking water of the revised Drinking Water Directive (to be adopted soon).
- Systematic control of authorisations - one could envisage a combination of an obligatory internal production control (GMP, good manufacturing process) with an external product control by an accredited inspection body.
- Industry must pay for authorisations, renewals and market surveillance – a fee system must be introduced for the authorisation of substances and materials (as in REACH or the Biocidal Products Regulation) payable to EFSA. REACH authorisations are granted only to the applicant and only for a specific use (and for a limited period). The current system for plastic materials, which allows anybody to use an authorised substance, must be dropped – all uses by all manufacturers must be authorised and subject to a fee separately. In addition, industry should pay a market surveillance fee payable to Member States' enforcement agencies. In the long run, one could even envisage a system where all toxicity and analytical tests necessary are conceived and commissioned by EFSA at the expense of industry. It goes without saying that such a payment structure would reduce the amount of substances to be evaluated considerably, and thus would make the system far more manageable.

CONTENTS

1 | INTRODUCTION - fundamental deficits of the FCM regulatory framework

The EU legislative framework for chemicals in consumer products in general - and for FCM in particular - is deficient. Its shortcomings, gaps and inefficient working methods have been criticised for a long time. In fact, only for plastic materials in contact with food does comprehensive legislation exist (Commission Regulation (EU) No 10/2011). However, this directive is also not complete, lacking specific provisions for solvents, colourants, aids to polymerisation and non-intentionally added substances (NIAS). Apart from that, the Commission has failed to maintain the Regulation by regularly reviewing its provisions (e.g. specific migration limits, SMLs).

In July 2012, the Commission published a "Roadmap" entitled "Food Contact Materials - Specific provisions for materials other than plastics – implementing measure" which referred "*to criticism by Member States, Industry and the European Parliament on the lack of EU specific legislation for materials other than plastics*". The Roadmap was intended to "*focus on the safety of these other materials and in particular those for which there is a high risk from transfer of its constituents into food (printing inks, coatings, silicones, adhesives, rubber, metals, paper and board and combinations of materials)*". The authors put it bluntly: "*Materials on the market are not safe*" – surprisingly frank for a Commission paper. However, the foreseen "Impact Assessment", which was envisaged to be initiated in September 2012, was incomprehensibly dropped by the Commission.

Valuable work from the EFSA Scientific Cooperation (ESCO) Working Group, published in 2012, was lost at the same time. Its aim was to compile and assess lists of evaluated substances used in Member States for non-plastic materials. This could have been a good departure point for the preparation of implementing measures in this area. Thereby valuable time was lost to fill the gaps, and consumers continue to be exposed to substances migrating from FCMs into food that are not properly assessed. Curiously, the Commission launched another roadmap concerning the "Evaluation of Food Contact Materials (FCM)" in 2017 "*to assess whether the current EU legislative framework for FCMs is fit for purpose and delivers as expected*". The text of the roadmap suggests that the Commission was unaware of the problems associated with this legislation, despite its own critical assessment made previously(!). This experience does not encourage confidence in the current evaluation process, or willingness of the Commission to address the problems with the seriousness required.

The European Parliament adopted a resolution on the implementation of the FCM Regulation in October 2016[1]. It clearly stated that "*materials not regulated by specific EU measures can pose a risk to public health and give rise to loss of consumer trust, legal uncertainty and increased compliance costs for operators*" and that "*the lack of*

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016IP0384

uniform measures is detrimental to public health and the protection of the environment, and to the smooth functioning of the internal market".

It underlined that "*shortcomings exist in the implementation and enforcement of the legislation in place*" and urged the Commission to adopt specific measures for materials not yet regulated at EU level, particularly for paper and board, varnishes and coatings, metals and alloys, printing inks and adhesives. The EU Parliament also identified a "strong need" for the revision of certain specific EU measures, in particular Council Directive 84/500/EEC on ceramics.

2 | Ceramics - no results after 8 years of discussion

The long overdue revision of the ceramics directive from 1984 represents a further failure in the EU FCM policy. It has been known for at least 10 years that the limits for cadmium and lead are outdated. EFSA scientific opinions on acceptable levels for these metals were published in 2009 and 2010 respectively. It was also known that provisions for additional metals should be incorporated. Discussions on a revision started in 2012 but have still not resulted in a Commission proposal. The meagre outcome of years of debate was an "Inception Impact Assessment" published in 2019, indicating a return to the beginning.

3 | FCM Printing Inks – another initiative gets stuck

Following the notification of Germany to adopt national legislation on printing inks for food contact materials in 2016, the Commission became active for a short time and indicated its intention to regulate this group of substances. In 2017, some thoughts were (informally) presented on two possible options[2]. The first ("Solution I") was to go for the establishment of positive lists and migration limits based on EFSA assessments in the same way as for plastic materials (Regulation 10/2011). It became clear that this was not the favoured option of the Commission which stressed its shortcomings, among others being a slow process (evaluation of only 25 substances per year by EFSA), inability to cope with a huge number of substances (pointing to the notified German draft regulation containing 700 substances and the Swiss regulation listing around 5000 substances) and lack of resources. A critique of the flawed procedures or lack of action on its own part, and options to improve the traditional system, were outside the scope of the Commission considerations.

Hence, a second option ("Solution II") was presented which placed assessment by accredited "designated bodies" ("commercial laboratories" and "other consultants") as the central panacea. These "independent" bodies were supposed to identify relevant substances, determine their migration and assess their toxicity (and conduct, where necessary, toxicity tests) resulting in a final approval ("compliance certificate") to be documented and stored in a database ("access to all information" for Competent Authorities and EFSA). The role of the legislator was thus intended to be diminished to ensure an appropriate accreditation system; to establish basic rules including guidance documents to be followed by the designated bodies; to supervise the work of the designated bodies (and to intervene if required) and to conduct market controls. In addition, a Governance Committee, including EFSA and Competent Authorities as well as stakeholders, was proposed to direct the work.

The second option – written in the spirit of privatisation, deregulation and liberalisation – seems to have been inspired by the papers written by the recently-retired Swiss civil servant, Dr Konrad Grob, then of Kantonales Labor Zürich. Dr Grob is undoubtedly a reputable and excellent expert in the field of FCM, and has correctly identified serious flaws in the present legislative framework for this kind of products. He has criticised the status quo in a series of publications, based on decades of practical experience. However, several measures he proposes point in the wrong direction and may even constitute the wrong precedent for other sectors. Hence, we need to react to some of his principal thoughts, and the related Commission considerations concerning printing inks, as outlined below.

Finally, this Commission initiative on printing inks was also put on hold.

[2]https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_wg_20170504_presentation_regulating_printed_fcm.pdf

4 | Key concepts proposed in papers on FCMs by Dr Grob

In the following, a few key issues are addressed responding to proposals by Dr Grob as outlined in his papers, in particular, "*The European system for the control of the safety of food-contact materials needs restructuring: a review and outlook for discussion*", 2017,[3] and "*The role of the European Food Safety Authority (EFSA) in a better European regulation of food contact materials – some proposals*", 2019[4]. The quotes below are from these two papers.

4.1 The large gap…

"*There is a large gap between the required safety assessment and the reality*". We wholly agree with this statement. In theory, all FCMs should be safe in view of Article 3 of the European Framework Regulation (EC) 1935/2004, which provides that materials and articles shall not transfer their constituents to food in quantities which could (a) endanger human health, or (b) bring about an unacceptable change in the composition of the food or (c) bring about a deterioration in the organoleptic characteristics thereof. Unfortunately, these requirements remain only empty phrases in the absence of detailed rules which draw the line between the acceptable and the unacceptable. As outlined earlier, specific rules are missing for most groups of materials and articles that may be covered by specific measures according to Annex I of the Framework Regulation. Where they exist, they are incomplete or deficient. Although positive lists for plastics focused on "monomers and other starting substances", "additives excluding colorants", "polymer production aids excluding solvents" and "macromolecules obtained from microbial fermentation", the final materials or articles were considered only peripherally.

"*A basic weakness of the concept is the focus on the substances used, while the reaction products and impurities ("non-intentionally added substances", NIAS) were largely left out, although they mostly constitute the majority in the migrates*". In some cases, such as coatings, the migrates consist of such reaction products almost exclusively.

Thus, the assessment of risks and assurance of legal compliance was deferred to industry. In theory, enforcement agencies should have verified the adequacy of industry compliance work. However, as Dr Grob recognises, "*in most EU countries the capacity of enforcement is far too small (and mostly further shrinking)*". It is not a surprise enforcement agencies were not in the position to check compliance documents from manufacturers and their suppliers, often outside their countries – not least because: "*Most control authorities do not yet have the expertise to check risk assessment*". In fact, Dr Grob impressively describes the difficulties encountered, including the uncooperative behaviour of industry in providing adequate documentation (i.e.

[3] https://www.tandfonline.com/doi/full/10.1080/19440049.2017.1332431
[4] https://www.tandfonline.com/doi/full/10.1080/19440049.2019.1662494

documentation supporting the "Declarations of Compliance", DoC). Less scrupulous businesses could therefore play a game of risk and wait for legal action or interventions by (overstrained) state authorities, action which indeed did not normally come.

Whilst the analysis is perfectly fine and convincing, the solutions presented by Dr Grob are not. On the contrary, the cure suggested may be worse than the disease. In the following, we explain why the proposed solutions – (more) industry self-control supported by private certification bodies - are questionable and may even exacerbate the problems at stake significantly.

4.2 Industry self-control

It comes as a surprise that Dr Grob understands the failure of a system of based on industry self-control, and recognises some businesses use every opportunity to escape from obligations ("*self-control of industry has repeatedly turned out to be prone to weaknesses and tricks*"), yet sees the future as more industry self-control: "*In the long run, the focus of the authorities might change from evaluating the substances used and regulating migration testing to the evaluation of the compliance work performed by industry, which means moving from legislation supporting industry towards checking self-control*". Or in other words: "*Taking this into account, the focus of the regulation should shift towards implementing and supporting self-assessment by the producers and harmonised control by the control authorities*". In our view, this is precisely the approach that has failed.

It is absurd to assume that authorities will be in the position to check risk assessments by industry – one can check risk assessments only by performing risk assessments (assuming the industry will indeed provide adequate documentation, something not always the case). But this is an extremely resource-intensive undertaking. Therefore, rarely is action taken against products based on risk assessment, requiring authorities to defend their risk assessments vis-à-vis assessments performed by industry. For example, in RAPEX we can find typically notifications of products exceeding regulatory limits (e.g. phthalates in toys) but hardly ever on the basis of a risk assessment.

The authorities themselves do not seem to be keen on following this track. In the 2012 Roadmap cited above, this was clearly spelled out by inspectors saying that "*only when specific parameters, criteria or limits are available in legislation or guidance against which compliance can be assessed, inspectors are able to verify compliance. Control authorities are often not in a position to establish those parameters, criteria or limits on a case by case basis. Current national and EU legislation has not established sufficient parameters to ensure the enforceability*".

It does not help to call for adherence to EFSA guidance. Risk assessment guidelines can be interpreted in many ways – at the end, the question is what is the "correct" interpretation of the guidance papers. This is why independent scientific committees have been established at the EU level. If adherence of risk assessment guidance would be sufficient to arrive at conclusions protecting citizens, we would not need these committees at all. Any industry committee could do the job. Hence, as long as there is

no assessment that is independent of industry, the level of protection will remain questionable.

Oddly, this seems a repetition of the debates that led to the adoption of REACH. In the 1990s, the chemicals regulation (particularly the "Existing Substances Regulation, ESR, Council Regulation (EEC) No 793/93) dealing with assessment of substances on the market before 1982) was judged insufficient, and the lack of progress and insufficient capacity of the authorities to conduct risk assessments was deplored. Then came REACH, essentially based on self-regulation (registration is the predominant part) with a lot of fanfare suggesting strict control by authorities: industry must shoulder the responsibility and must provide the proof for the safety of chemicals ("REACH places the burden of proof on companies", "no data, no market"). In fact, the bottleneck today is the same as it was before, and authorities can check only a small fraction of the dossiers in the so-called substance evaluation. So industry must provide the proof is just an empty phrase for the largest part of REACH – in most cases, no-one is there to judge whether the proof has been done. It can only be illogical to make industry responsible while industry defines what "responsible" means.

But irrespective of the above – even if we assume the best intentions by industrial players – it remains in the dark how they should cope with hundreds of substances migrating from materials. Even if these substances can be identified and quantified (which will often be difficult), toxicological data, upon which risk assessments can be performed, will be missing. Why should industry be better positioned to assess such substances than the authorities were in assessing bisphenol A, diglycidyl ether (BADGE), isopropylthioxanthone (ITX), or mineral oil fractions (MOSH/MOAH)? And after all, why should self-assessments by different players arrive at the same conclusions? A harmonised approach cannot be expected.

We support the view expressed in a commentary by J. Muncke et al.: "Scientific Challenges in the Risk Assessment of Food Contact Materials, 2017[5] suggesting that "*Based on our assessment of the available evidence, we conclude that the current approach of premarket, prospective RA of chemicals in FCMs is insufficient to protect public health. It relies too much on self-assessments by industry and assumptions that do not reflect contemporary scientific knowledge, lacks clear guidance, and cannot be enforced by authorities*".

Conclusion 1 by ANEC:

Industry self-assessment in the field of food contact materials must be much reduced, rather than strengthened. By contrast, assessments by national authorities and EFSA, that are independent of industry, must be considerably reinforced.

[5] https://ehp.niehs.nih.gov/doi/10.1289/EHP644

4.3 Risk assessment by accredited private bodies

Dr Grob understands the limitations of enforcement agencies to verify safety assessments by industry and to take action against unsafe products: "*Enforcement authorities are weak drivers for implementing safety assessment for FCMs, as resources are scarce and effective measures against non-compliant products are largely missing*". His proposed way out of the crisis: "*Private bodies certified in performing risk assessment according to EFSA guidance might be needed to step in*" and, finally, these bodies should more or less take over: "*Given the very few resources of the competent authorities, as much as possible of the control should be transferred to private institutions*" (our emphasis).

This approach leads in the wrong direction. De facto legislative powers would be moved to "independent" private bodies, which would decide on the type of (migrating) substances and the maximum acceptable levels. We doubt there would be "control". The results of the industry self-assessments (voluntarily) confirmed by private certification bodies, i.e. approved substances and materials with acceptable levels of migrating contaminants (in theory checked by authorities using document control) are proposed to be listed in addition to substances and materials approved by EFSA, assuming that certified materials will be favoured by manufacturers of FCMs, packers and the food industry (see more details below).

One might argue that this approach may nevertheless constitute an improvement compared to the current situation, one where industry is charged to carry out safety assessments in the absence of detailed rules and with little control. Private bodies – accredited to adhere to available EFSA guidance - would introduce competence and a (more) neutral perspective ensuring the avoidance of a commercial bias. This is fundamentally wrong for two reasons: first, private certification bodies are not (necessarily) neutral and, second, the approach will pave the way for a system of food contact material legislation where – unlike in the current plastic materials legislation - hardly any detailed substance-specific provisions will be set for materials not yet covered by implementing measures, as the Commission envisaged for printing inks. Thus, the regulatory system would be driven into a quasi self-regulation by industry and private bodies, without democratic legitimisation. It also seems doubtful whether the assessments by these bodies could be consistent or easily aligned.

4.4 "Independent" testing, certification or inspection bodies

Private certification bodies are meant to be "independent". On the contrary, these bodies operate in highly competitive markets, and their commercial interests will always be in a permanent state of tension with their presumed impartiality. There are numerous examples of the fundamental failure of the bodies meant to ensure a check-and-balance on businesses, but which did nothing of the sort. Dr Grob acknowledges the need for "*preventing competition in terms of "easier" approval*" but does not elaborate on how this could be done. In fact, it is a mission impossible.

4.4.1 Wirecard and other audit failures

The "Wirecard" scandal attracted a lot of media attention in summer 2020. The German company, which offered electronic payment transaction services, was forced to file for insolvency. Its CEO Markus Braun was arrested. The company is suspected to have engaged in a series of accounting frauds – it appears that approximately € 1.9bn (a quarter of its balance sheet) was missing from the accounts. Wirecard admitted that this money may not exist.

It is surprising that the long-time external independent auditor (as of 2007) of the company - E&Y (Ernest & Young) – had not discovered any irregularities over many years and repeatedly confirmed a clean bill of financial health. Only at the end did E&Y refuse to sign off Wirecard's financial statements for 2019, and accused the firm of "elaborate fraud". However, this did not protect E&Y from fierce attacks, including a lawsuit by a lawyer for private investors claiming that the audit company failed to flag improperly booked assets.

Green and liberal members of the EU Parliament subsequently called for a reform of EU accounting rules to address inter alia the inherent wrong incentives in statutory auditing: "*Such incentives arise because accounting firms are selected and paid by the companies they audit. As customers, the audited companies can freely hire and dismiss their own auditors. Moreover, all big accounting firms also engage in consulting and sell advisory services to audited companies. As a result, accounting firms have strong incentives to please their customers rather than to exercise scrutiny*"[6].

Wirecard is only the latest in a long history of accounting scandals. For instance, Enron, the US energy company based in Texas, went bankrupt in 2001. It was the largest corporate bankruptcy in US history at the time (until the WorldCom scandal soon after). Enron has even become a symbol of corporate fraud and corruption. The scandal also represented a major audit failure. Again, an external independent auditor (Arthur Andersen) had given its blessing for a long time.

4.4.2 The big financial crisis and the role of rating agencies

In 2007/2008, the world was shaken by a serious global financial crisis resulting in an economic depression ("The Great Recession"). At the beginning, the real estate bubble in the US burst – many house owners could not pay back their debts. These debts were traded by finance institutions as so-called "mortgage-backed securities" and included "sub-primes" (credits given to people of low creditworthiness). These papers offered initially high interest rates, but later were considered to be almost worthless "toxic" assets dragging their holders (such as banks) into the abyss.

"Independent" credit ratings agencies played a highly questionable role in this disaster by providing exaggerated ratings of risky mortgage-backed securities, thus giving investors false confidence that they were safe investments. Many of these papers were given AAA ratings, indicating the highest and safest investment grade. In fact, the rating

[6] https://sven-giegold.de/en/liberals-and-greens-call-for-wp-reform/

agencies were (and still are) paid by the issuer of the financial product. Critical and objective assessments would only disturb the business. As the proverb goes: "He who pays the piper calls the tune".

4.4.3 Dieselgate

In the aftermath of the "Volkswagen emissions scandal", also known as "Dieselgate", the European Commission proposed a revision of the regulation "*on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles*" (COM(2016) 31 final) in January 2006. In a great moment, the Commission identified a major shortcoming in the current system where test facilities performing the official type-approval testing are directly paid by car manufacturers. In a recital (17), this is expressed as follows: "*The independence of technical services vis-à-vis manufacturers should be ensured, including by avoiding direct or indirect payments by the manufacturers for the type-approval inspections and tests they have carried out. Therefore the Member States should establish a type-approval fee structure that should cover the costs for carrying out all type-approval tests and inspections carried out by the technical services designated by the type-approval authority, as well as the administrative costs for issuing the type-approval and the costs for carrying out ex-post compliance verification tests and inspections*". It is a shame that this proposal did not get sufficient support from the Member States and the EU Parliament. Most regrettably, the adopted regulation ((EU) 2018/858) does not forbid that testing facilities are paid by manufacturers. Member States may only charge fees for the type approval itself and may levy fees for the designation and monitoring of technical services. Nonetheless the Commission thoughts on conflicts of interest resulting from commercial relationships between manufacturers and test (or inspection) bodies are highly relevant, and not only in the car sector.

4.4.4 EMAS

The breaking of commercial ties between the commissioner and the control bodies was also called for in a joint position paper of ANEC, ECOS and EEB concerning the last revision of the EMAS (eco-management and audit scheme) Regulation in 2008[7]: "*In order to ensure that the strong competition between agencies providing verification services will not become a race to the bottom (where the interest to please the client is more important than a critical assessment), it should be stipulated that the contract is not made between the organisation and the verifier but between the competent body and the verifier*". Unfortunately, the call was ignored by decision makers.

Conclusion 2 by ANEC:

The development of detailed specifications for food contact materials must under no circumstances be moved to private bodies financially dependent on suppliers. However, one might consider that EFSA and national governments could commission work to

[7] https://ecostandard.org/wp-content/uploads/emas-anec-env-2008-g-037final.pdf

private institutes e.g. for conducting standardised toxicity tests or ensuring continued compliance of production with authorised substances and materials.

4.5 Control of risk assessment documentation

Dr Grob's flawed approach to move FCM regulation towards industry self-assessment, verified by private bodies subject to governmental control, suffers from several shortcomings and would necessarily lead to a dead end.

- First, approval and listing of new substances to be used prior to placing products on the market is replaced by a post market surveillance system: "*Accordingly, regulation should shift the focus from the pre-use evaluation of substances (by EFSA or national risk assessors) towards the control of the safety of the substances migrating from FCMs on the market (by the control authorities)*". In other words: as a matter of principle, dangerous products may be placed on the market as long as corrective action by authorities takes place.

- Second, this corrective action may never come as a result of resource constraints of enforcement bodies. As Dr Grob puts it: "*In many European countries, the authorities responsible for the control of FCMs only consist in total of one to three persons; in most others it is less than 10, possibly even distributed over several sites. No adequate control can be built with these resources*". This is true, particularly when authorities are committed to resource-intensive risk assessments which are a "conditio sine qua non" for any reasonable document control. Even if (exceptionally) an authority identifies a problem based on a risk assessment, it does not mean it can be quickly solved. Industry may not agree with the evaluation by authorities, or further data may be required so prolonging the process.

- Third, the proposed involvement of private bodies does not help much as the control of the controllers is as resource intensive as the control of industry self-assessments – unless the private bodies are a substitute of governmental control – and that is the very essence of the matter. It can be assumed that the role of authorities will be limited to "*spot checks*" to maintain a semblance of regulatory oversight. Note: Dr Grob seems to have in mind that authorisations can be granted by national authorities and private bodies, whilst, in the Commission's reflections on a possible printing ink regulation, authorisations by only private bodies were foreseen (in practice, however, the difference would perhaps be marginal, as authorisations by national authorities would probably be the exception rather than the rule).

- Fourth, it remains entirely unclear why a post market surveillance system based on numerous risk assessments of numerous actors including numerous companies, private bodies and enforcement agencies should be more efficient and lead to better results, than a single risk assessment by a single institution done once prior

to placing a product on the market. For instance, it would seem rather odd to allow industry to use all kinds of printing inks and then start at the level of enforcement to verify whether a certain manufacturer in the FCM supply chain – voluntarily or obligatorily stamped by a private body - has properly assessed the substances used. It seems quite obvious that this would not only result in a significant duplication of work, but also in different conclusions and, finally, in authorities (even more hopelessly overburdened than today) arriving at different acceptance levels (if any). In fact, the whole approach by Dr Grob is nothing else than passing the buck from the present to the future, assuming solutions where there are none.

- Fifth, it is also entirely unclear how the variety of assessments by various actors should be rectified to ensure harmonised results. Dr Grob just talks about the need for harmonised procedures for document control and assessments without giving many details: "*The procedures, requests, justifications, timelines as well as the evaluation should be equivalent throughout Europe*". For example, he talks about document collection centres conducting some initial toxicological screening, and a "*coordinated document management system*" (including letter templates, guidance papers, checked materials, summary evaluations, etc.). However, final assessments – "*in accordance with EFSA guidance*" - are to be performed by toxicologists "*since toxicological evaluation is not routine and cannot be completely covered by guidance*". Dr Grob envisages that national authorities will build up risk assessment expertise and play a key role in the process. Only in exceptional cases should EFSA be involved: "*Difficult and controversial cases should be assessed by an institution recognised throughout Europe, which is EFSA. EFSA should also be ready to be referred to for arbitration*". On that basis, it seems wishful thinking to prevent "*that the more than hundred European control authorities reach different conclusions and disturb the market*" unless one realistically assumes that such enforcement activities will be the very exception as in the past.

- Sixth, it is not even clear how the access to the risk assessment documentation ("compliance documentation"), and its quality, along the supply chain should be assured. These companies may not even be situated in Europe: "*Typically the producers are scattered over much of the world, but the authority checking the compliance work does not know where*". Dr Grob himself gives examples of unsuccessful attempts made in the past to check this documentation. Why should it work better in future?

Conclusion 3 by ANEC:

Dr Grob's approach constitutes a "disimprovement" of the current system claimed not to be fit for the purpose. By contrast, the proposed changes would – if implemented - lead to less efficiency, less consistency and less consumer safety.

4.6 Listing of approved materials

Finally, the "approved" substances and materials will be listed and thus become quasi legal requirements: "*Once approved, both substances and materials should be listed in a manner allowing public access in order to ensure consistency in a harmonised market and to make the best use of the work. Hence, the list of authorised substances should be opened to substances approved through document control, and materials should be added to the list of materials approved by EFSA and national risk assessors (official control might even become a main source of entries). This presupposes, however, that the evaluation is properly done*".

Dr Grob's approach is ambiguous in terms of final decision-making on substances and materials to be listed as a result of the document control. On the one hand, it is stated this is done by national authorities (exceptionally by EFSA) – on the other hand, it is said that the latter are just doing spot checks. Realistically, it can be expected that substances and materials found appropriate by private bodies will enter the list, given the limited capacity of national enforcement bodies. In fact, this was the solution considered by the Commission in the printing ink case (see above).

At the end of the day, a system of democratic decision-making as regards acceptable substances or materials (including restrictions and migration limits) is suggested to be replaced by a kind of legislation through enforcement, where results of enforcement activities become law and the relevant decisions are deferred to private bodies bypassing the democratic institutions. It could be doubted whether such an approach conforms to the EU Treaty.

Conclusion 4 by ANEC:

The proposed approach by Dr Grob undermines democratic decision-making by deferring authorisation on acceptable substances and materials to private bodies. Even if such decisions were to be controlled (to some extent) by national authorities, they cannot be seen as a replacement of a democratic process.

5 | The alternative – reduce FCM substances/materials and let industry pay

The alternative promoted by ANEC is based on the following principles:

- Radical reduction of substances and materials
- Elimination of substances of concern in all types of FCM
- Pre-market authorisation for substances and materials
- Expiry date for all authorisations
- Systematic control of authorisations
- Industry pays for authorisations, renewals and market surveillance

5.1 Radical reduction of substances and materials

Some believe industry can use as many substances and materials as it wants, as long as no-one provides evidence they are hazardous to health, and that it is the role of state bodies to try to find the evidence while lagging behind in an unequal race between the hare and the tortoise. It is not a law of nature that EFSA can evaluate only a few dozen or so substances annually, whilst thousands of substances would need an assessment, so making the undertaking hopeless from the start. The solution can only be to increase the capacity of EFSA considerably, by ensuring a significant increase of its funding and reducing its workload by drastically reducing the number of substances and materials for evaluation. If industry wants to use thousands of substances and materials, it may do so but should pay for each assessment and each authorisation for each use (and for market surveillance). It can be taken for granted that this will significantly reduce the appetite for substances to be used. The rule of the game must be changed in line with the further points below.

5.2 Elimination of substances of concern in all types of FCMs

A first and quick measure is to ban all substances of (high) concern in all FCMs, e.g. identified SVHCs, classified CMRs, PBTs, vPvBs, as well as established EDCs on a case by case basis following a prioritisation programme. Exceptions may be granted by EFSA if justified. These bans are of particular relevance where a positive list of authorised substances is not (yet) available.

5.3 Pre-market authorisation for substances and materials

As a matter of principle, not only substances used in the production, but also final materials must be authorised by EFSA prior to placing FCMs on the market in the long run. Material authorisation must include NIAS using, where appropriate, the threshold of toxicological concern (TTC) approach supported by EFSA ("Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment",

April 2019[8]): "*The approach can be used when the chemical structure of the substance is known, there are limited chemical-specific toxicity data and the exposure can be estimated. The TTC approach should not be used for substances for which EU food/feed legislation requires the submission of toxicity data or when sufficient data are available for a risk assessment or if the substance under consideration falls into one of the exclusion categories*". However, bearing in mind the uncertainties of the approach, every effort should be made to fill toxicological gaps to conduct a proper risk assessment. Therefore, as far as possible, the TTC approach should be applied temporarily, and missing toxicological data should be generated for the most relevant substances following a priority programme.

Dr Grob highlights an interesting issue: "*Many materials described in the petitions are experimental and probably never brought to the market*" and "*The restrictions in use derived by EFSA from the application described by the petitioner may not be adequate for the materials containing the substance that really reach the market*". Bearing in mind that the triggers for the extent of toxicity tests required for authorisation of substances are dependent on the level of migration measured using these "experimental" materials, the question arises whether the migration behaviour of the substances in marketed products is comparable. This issue deserves further research and discussion, but one option may be to require confirmation of the assessment including migration results using materials from the real production.

Muncke et al (paper quoted above) raised another important issue: *"…the E.U. Reference Laboratory for FCMs recently reported that standards for analytical method calibration are available for only 53% of FCCs currently authorized for use in plastic FCMs (Simoneau 2015). This implies that concentrations of about 440 authorized FCCs cannot be quantified and, consequently, in Europe, legal migration limits cannot be enforced*". This is entirely unacceptable. Where migrating substances (intentionally or not intentionally added) from materials cannot be determined and quantified, the material should not be approved.

Of course, the approach outlined above cannot be put into practice in the short term, and will need a staged implementation prioritising certain substances and materials, as well as transition periods.

The approach chosen will also depend on the type of material. For those such as plastic materials, rubber, coatings, adhesives, paper and board or printing inks, the current approach for substance approvals in plastic materials, complemented by final material approval, seems appropriate. Rules can be based on existing national legislation or guidance documents (at least for an interim period). The approach taken for plastic materials may serve as a model for the gradual implementation of harmonised rules. When the implementing measure was adopted in 1990 for the first time (Commission Directive 90/128/EEC) a complete list of authorised substances could, of course, not be established. The harmonised list comprised just around 170 substances (now more than 1000). Thus substances which were approved in at least one Member State were

[8] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5708

allowed to be used pending a decision on inclusion in the Community list. These substances were listed in Annex II, Section B (around 400 substances). Member States were not allowed to authorise additional substances except for a limited period of 2 years.

However, the situation for some other materials is different. As an example, it needs to be discussed whether e.g. (all) metals and alloys need approval (e.g. specifying acceptable stainless steel grades) or whether it is sufficient (in certain cases) to limit the content and/or migration of certain metals. Similarly, glass and ceramic materials may be acceptable provided that migration of certain metals is restricted. In case of wood, the usable types of wood and the permissible surface treatment will have to be defined to exclude undesirable migration (also from food into wooden articles such as wooden spoons or chopping boards), and the absence of cracks and decay needs to be ensured. In other words, different approaches for different materials will be warranted. A strategy for this should be developed, following a priority programme based on existing national legislation or guidance documents using the 2016 JRC baseline study[9] "Non-harmonised food contact materials in the EU: regulatory and market situation" as a departure point.

5.4 Expiry date for all authorisations

In general, an expiry date (e.g. 5 years) must be set for approved substances and materials, in line with future provisions for materials in contact with drinking water in the revised Drinking Water Directive that will be adopted soon. After this period the authorisation must be renewed.

It is easy to envisage that the implementation of this principle in the field of plastics materials would immediately considerably shrink Annex I of Regulation 10/2011 (consisting of more than 1000 substances), so making maintenance of the regulation much easier.

5.5 Systematic control of authorisations

The authorisation of substances and materials must be accompanied by a systematic external monitoring of continued compliance of manufactured products. This should not only comprise an internal production control in accordance with the Commission Regulation "on good manufacturing practice for materials and articles intended to come into contact with food" ((EC) No 2023/2006), but also include external product control.

A combination of external initial type testing (confirming that the product is in conformity with the relevant specification), internal production control by the manufacturer and external testing of samples is, for example, used in the Construction Products Regulation (CPR, Regulation (EU) No 305/2011) as one of the systems of assessment and verification of constancy of performance (the highest one, for products which may seriously affect health and safety of people). It is referred to as "System

[9] http://publications.jrc.ec.europa.eu/repository/bitstream/JRC104198/en_jrc104198_fcm%20baseline%20final%20report%202017-01-16_all.pdf

1+". Type testing and testing of samples is done by a notified body (i.e. a third-party product certification body).

In case of FCM, one could envisage a combination of an authorisation of substances and materials (by the Commission after consultation of EFSA) with internal production control and external product control by an accredited body. The latter might be contracted by the national authority and not be paid by business. The use of a private accredited certification body may be acceptable for this purpose as it would only confirm continued compliance with the authorisation conditions, rather than defining acceptable substances and materials (including migration limits). Hence, the role of the accredited bodies suggested here would be quite different compared to the one envisaged by Dr. Grob and the Commission.

The role of national authorities could thus be limited to conduct spot checks to ensure that the production and products is in conformity to legal provisions (and, possibly, to hire certification bodies for product control). This would free capacity for monitoring the legislative approval process.

5.6 Industry must pay for authorisations, renewals and market surveillance

The system proposed above needs adequate funding. Muncke et al (quoted above) supported "*an approach where manufacturers seeking authorization pay into a common fund that is used by authorities to commission migration and toxicological tests by independent third parties that do not have a conflict of interest*". We believe that industry should not only pay for conducting tests, but also for the assessment of substances and materials by an expanded and strengthened EFSA, as well as continuous production control by certification bodies and the enforcement of the system.

In the food sector, it is already common practice to invoice industry for the costs of market surveillance. The Regulation "on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products" (Regulation (EU) 2017/625) contains rules for mandatory inspection fees – either at the level of the cost of the enforcement activities or in accordance with the amounts provided for in its Annex IV (subject to exemptions). Obviously, it was understood that the necessary enforcement activities cannot be paid from the state budgets and need additional funding. The system exists for many years and was even strengthened in 2017. There is no reason why a similar approach should not be possible in the FCM field, with fees payable to national market surveillance authorities.

In addition, authorisation fees should be introduced. The FCM evaluation study "Study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004)" of July 2020[10] points out that companies have to pay fees under REACH

[10] https://op.europa.eu/en/publication-detail/-/publication/3ae0294b-bc0c-11ea-811c-01aa75ed71a1/language-en

and the Biocidal Products Regulation in addition to other costs incurred (e.g. for toxicity tests and preparing a dossier). The following table (Table 33, page 94) showing average figures is presented in the report:

Comparison of costs for industry for the inclusion of substances in positive lists

Application costs	Regulation on plastic FCMs	Plant protection products[147][148]	Biocide products[149]	REACH[150]
Fees (1,000 EUR)	0	0	50 to 150[151]	40
Dossier preparation (1,000 EUR)	500	2,000 to 40,000	3,000 to 5,000	310

Fees under REACH are regulated by the Commission Regulation "on the fees and charges payable to the European Chemicals Agency…." (Regulation (EC) No 340/208 as amended[11]). It includes fees for (reviews of) authorisations (Annexes VI and VII) depending on the size of the companies (standard fees and reduced fees for medium, small and micro enterprises). The standard fees for authorisation currently are: EUR 54.100 (base fee), EUR 10.820 (additional fee per substance) and EUR 48.690 (additional fee per use). The lowest fees for micro enterprises are 10% of the above. Fees under the FCM regulation should, of course, be payable to EFSA.

Fees under the Biocidal Products Regulation are regulated by the Commission Implementing Regulation "on the fees and charges payable to the European Chemicals Agency …" (Regulation (EU) No 564/2013 as amended[12]). Here the fees are considerably higher compared to REACH authorisations – for example, in case of an approval of an active substance, EUR 120.000 are due for the first product-type for which that active substance is approved. The additional fee per additional product-type is EUR 40.000. There are also discounted rates for smaller companies.

As already described in the text above regarding the Volkswagen scandal (4.4.3), the Commission had (unsuccessfully) proposed that the Member States charge a type-approval fee, including all necessary tests, to avoid that test houses are paid by the manufacturers themselves. If the proposal had been adopted, industry would have had to pay not only a fee for authorisation, but also for the type testing of the car. Similarly, one could envisage - at least in the long term - a system where the FCM producer is charged an authorisation fee and the costs for all analytical and toxicity tests to be commissioned by EFSA.

The FCM evaluation study raises another important point: "*With currently harmonised FCM, once a substance is authorised, it can be used freely by any competitor, while only the applicant incurs the costs of submitting the application and preparing the application dossier*". This is an entirely unacceptable condition. In REACH, authorisations are granted only to the applicant for a specific use (and for a limited period). This system must be implemented in the FCM field. Any further use and any further company wishing

[11] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R0340-20180715
[12] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02013R0564-20141119&qid=1598434994390&from=EN

to use an authorised substance must submit an application and, of course, pay all fees. This will promote joint applications.

Conclusion 5 by ANEC:

In future, the number of substances and materials for evaluation must be radically reduced. Certain substances of (high) concern, such as SVHCs or CMRs, should be banned in a generic fashion in all FCM materials. Authorisation by the Commission, based on EFSA opinions, must include not only substances but also final materials. In general, an expiry date (e.g. 5 years) must be set for approved substances and materials. Internal production control (GMP) must be complemented by an external product control by an accredited body. A fee system must be introduced for the authorisation of substances and materials (as in REACH or the Biocidal Products Regulation) payable to EFSA. Authorisations should be granted only to the applicant and only for a specific use (and for a limited period). In addition, industry should pay a market surveillance fee payable to Member States enforcement agencies. One could also envisage a system where all toxicity and analytical tests are commissioned by EFSA at the expense of industry in the long run.

Acknowledgements

Special thanks go to Dr. Franz Fiala, main author of this paper.

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and the use of standards, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 34 countries.

ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.

Designed by AdGrafics.eu

ANEC

Raising standards for consumers

European association for the coordination of consumer representation in standardisation aisbl

Rue d'Arlon 80 – 4th Floor
B-1040 Brussels, Belgium

+32 2 743 24 70

anec@anec.eu

www.anec.eu

EC Register of Interest Representatives:
Identification number 507800799-30
BCE 0457.696.181

@anectweet

ANEC is supported financially by the European Union & EFTA

This document may be quoted and reproduced, provided the source is given.
This document is available in English upon request from the ANEC Secretariat or from the ANEC website at www.anec.eu © Copyright ANEC 2020