

Chapter 18

A tortuous and conflict-laden process: the revision of the directive protecting workers against carcinogens

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1. Paralysis for more than ten years¹

The revision of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD) was already foreseen in the EU strategy on workplace health for the period 2002-2006 (European Commission 2002). At that time, four aspects were considered as priority issues by the European Commission: the inclusion of reprotoxic substances in the directive's scope, the adoption of new occupational exposure limits (OELs) with a view to complementing the list of three substances in Annex III, the revision of the existing OELs, and the adoption of criteria for defining OELs.

In accordance with the procedures set forth in the Treaty, unions and employer organisations were consulted twice. The first stage of consultation was launched on 6 April 2004, while the second stage was greatly delayed, not starting until April 2007. At that time, the Commission was still committed to including reprotoxic substances in the directive's scope. The document launching the 2007 consultation stated the following: "the Commission intends to propose an extension of the scope of the Carcinogens and Mutagens Directive to include substances toxic for reproduction".

For its part, the Scientific Committee on Occupational Exposure Limits (SCOEL) had finished a major project, coming up with recommendations for several dozen CMR substances. The slow pace of the social partner consultation (three years between its two stages) did not at first seem alarming. In the context of progressively implementing REACH, it would have been logical to consider this revision as a top priority for the 2007-2012 strategy. The Commission Communication on this strategy (European Commission 2007) constituted a deregulatory turning point linked to the political context of the formation of the first Barroso Commission (which took office in November 2004). At that time, the European Trade Union Institute was to comment: "Future legislative measures are announced in the most diffident terms. The Commission says it will 'continue its work, through the ongoing consultations with the social partners, to find ways of improving prevention with regard to musculoskeletal disorders, carcinogens and needlestick infections'. Movement on the two biggest issues (carcinogens and musculoskeletal disorders) has been stalled for years. The Commission no longer even dares utter the word "directive" despite it featuring in the strategy for 2002-2006. So the Commission will continue its work between 2007 and 2012, but will it ever complete

1. The information contained in this chapter has been updated and is valid as of April 30, 2018.

it? After five years of fudging the issue, it could have given a clearer statement of what ‘ways’ it plans to ‘find’” (Vogel 2007).

In fact, the ambiguous wording of the strategy served to justify a legislative paralysis lasting more than a decade. The main factor was the European Commission’s ‘Better regulation’ policy orientation, under which any tightening of legislation protecting workers against occupational cancers was seen as creating obstacles to company profit-making. Considering that some 100,000 deaths each year in the European Union are the result of occupational cancers, the human cost of the ‘Better regulation’ campaign has been disastrous.

An Impact Assessment Board² was set up in late 2006 to make prior assessments of all legislative proposals, even before they were officially formulated by the Commission. Assessment criteria are vague. As board members obviously do not have the in-depth knowledge of all matters covered by EU policymaking, they tend to only intervene on formal aspects, with a major focus on costs and benefits. The relevance of this approach raises many questions, especially when it comes to making choices about complex regulations whose medium- or long-term consequences are highly hypothetical. In reality, this body is highly dependent on the Commission’s impact assessments. In a way, it has the role of a review committee for such assessments, fine-tuning them at a formal level. Assessments somehow anticipate predictable criticism or are modified as the result of an initial negative opinion or one with reservations. In 2014, the Commission put an end to inter-department consultation – previously indispensable for adopting a legislative proposal – in the case of the board issuing a negative opinion on the quality of an impact assessment. This power to block an initiative in advance thus prevents the sole EU body elected by universal suffrage, the European Parliament, from debating it.

Over the years, the requirements – set by the Commission itself – regarding the content of impact assessments have become increasingly complex. As a result, more resources are being devoted to cost-benefit studies than to the substantive content of legislation. Experience in the United States where strict and very formal cost/benefit rules were introduced in the 1980s illustrates the flaws inherent to a method where most of the data has to be extrapolated due to the high number of uncertainty factors. These flaws are not simple defects, instead leading us to what seems to be their key political purpose: opening up decision-making to the determining influence of lobbies and thereby sidestepping the possible disadvantages of a political system of representative democracy (Heinzerling *et al.* 2005).

With regard to the revision of the CMD, external consultants were commissioned to conduct two impact studies before 2014. The one involved 25 substances for which new or revised OELs were planned. It was completed in 2011 (IOM 2011). The other involved extending the scope of the directive to reprotoxic substances. It was completed in 2013 (Milieu and RPA 2013).

2. The Impact Assessment Board was replaced by the Regulatory Scrutiny Board set up under the 19 May 2015 decision of the Commission President.

By 2013, the Commission was thus in a position to adopt a proposal for revising the directive. The impact study on OELs was largely in favour of such a revision, while that on reprotoxic substances ended on a cautious note, as the available data on reproductive problems caused by occupational exposure was full of gaps. However, the latter study acknowledged that in two countries where these substances were included in regulations governing carcinogens (France and Germany), the impact had been positive from a prevention perspective.

In December 2012, the Barroso Commission launched 'REFIT', the 'Regulatory Fitness and Performance Programme' (European Commission 2012). Its goal was to review all existing European legislation (the *acquis communautaire*) and to submit any new initiative to competitiveness tests. This created a new obstacle in the way of revising the directive, not just requiring the hypothetical impact of any future legislative change to be considered, but also requiring a retrospective analysis of the supposed impact of already existing directives. Since 2 October 2013, REFIT has blocked all proposals aimed at improving workplace health legislation (European Commission 2013a). The initial plan was for this moratorium to finish at the end of the term of office of the Barroso Commission (November 2014), but it was extended for the whole of 2015 by the incoming Juncker Commission.

Justification for this policy came from the wide-ranging public consultation held by the Commission at the initiative of the Commissioner for Industry and Entrepreneurship, Antonio Tajani. Entitled 'Top Ten', this consultation called on SME heads to list any legislation they disliked (European Commission 2013b). Of the more than 20 million SMEs in Europe, just 628 responded. Adding to these a few companies from other corners of the world and a few employer organisations, one just about managed to scrape together 1000 responses. For the majority of countries, the number of responses was lower than 20. For a 3-month consultation, available in 21 different languages, with a large advertising budget, this turned out to be a total fiasco. The questions stank of manipulation as they were concerned only with the negative impact of legislation. The few SMEs that took part in this farce indicated that their 'pet hate' was everything to do with taxes. They also had no liking for having to treat their waste and inform consumers through labelling their products. The obligation to ensure the safety of chemical products was ranked seventh among the 'pet hates', immediately followed by health and safety at work. As regarded specific legislative acts, the 'pet hate' was REACH. In the field of health and safety, the CMD figured as one of the directives considered to be harmful by the employer organisations, but did not figure in the list drawn up by the respondent SMEs. Any serious polling institute would have binned these results. Biased questions, too few responses to constitute a representative sample, etc. The Commission, however, saw the survey as a source of certainties. In numerous official documents published at a later date, it stated having now identified the most onerous legislative fields. 'Top Ten' was to become a gospel truth, echoed from text to text without mention of the doubtful conditions of its birth.

On 6 June 2014, the Commission adopted an EU Strategic Framework on Health and Safety at Work 2014-2020. No legislative measure concerning occupational cancers was foreseen. The general drift of this document was clearly deregulatory, stating

that “In line with the objectives of the REFIT programme, a continuous joint effort by the Commission, other EU institutions and Member States is required to simplify EU legislation and eliminate unnecessary administrative burden. In the coming years, key concerns will be assessing whether existing OSH legislation is fit for purpose, examining how to improve its implementation, and ensuring better, effective and equivalent compliance across Member States and enterprises” (European Commission 2014).

The formation of the new Commission under Jean-Claude Juncker in 2014 brought no change to this approach. At her hearing by the European Parliament on 1 October 2014³, Ms Thyssen – designated for the employment and social affairs portfolio – listed four priorities for her work. Workers’ health and safety were not on her list. The word “cancer” was not mentioned once during the long hearing. The brief statement referring to European legislation on occupational risks was marked by the same fudging as seen over the past decade in the two Barroso Commissions.

The first work programme adopted by the Commission under Mr Juncker’s Presidency in October 2015 maintained this approach, with the revision of the CMD not listed among the legislative initiatives planned for 2016. The justification given for this standstill was that it was necessary to evaluate all existing health and safety legislation and that any changes could only be made after this had been completed.

2. The 2016 U-turn

The spring 2016 announcement that the Commission was finally going to relaunch the revision of the CMD might have come as a surprise as it ran counter to the priorities constantly reaffirmed between 2005 and 2015. There are various factors explaining this U-turn. They show that – even in a very unfavourable political context – the perseverance of union organisations swimming against the tide can end up creating sometimes unexpected alliances.

A growing number of Member States no longer accepted this legislative standstill, as increasingly seen from 2014 onwards. The opinion of these States was that it would be dangerous to have national economies competing against each other, to the detriment of protecting workers’ lives. They were also aware of the amounts spent on public health in association with treating cancer and of the effectiveness of cancer prevention focused on occupational exposure.

In March 2014, the Ministers of Labour from Germany, Austria, Belgium and the Netherlands addressed a hard-hitting letter to the European Commission demanding the revision of the CMD. Its tone was particularly insistent, highlighting the fact that more than 30 million workers in Europe were exposed to carcinogens and mutagens at unacceptable levels. It called for the directive’s urgent revision and recommended

3. The full minutes of this hearing are available at: www.europarl.europa.eu/hearings-2014/resources/library/media/20141022RES75837/20141022RES75837.pdf

the setting of binding OELs for fifty substances, reflecting a very large proportion of exposure situations. It also set forth criteria for setting these OELs.

In December 2014, the Council of ‘Environment’ ministers decided to join Sweden in a lawsuit against the European Commission for blocking the concrete application of a key part of the 2012 biocides pesticides regulation: the Commission was supposed to have defined criteria regarding endocrine disruptors by the end of 2013. While this debate had little to do with workplace health issues, it spotlighted a growing discontent with the Commission regarding the influence of industry lobbies on approaches to chemical risks.

On 9 March 2015, meeting at the initiative of the Latvian Presidency, the Council of ‘Social Affairs’ ministers demanded that the Commission start taking the initiative in revising the CMD. Within less than a year, the battle commenced by four Member States had got most other Member States convinced.

During the first half of 2016, the Dutch EU Presidency helped this objective take on concrete form. Already in the summer of 2015, the Dutch government had made it known to the Commission that it would be making the issue of occupational cancers the main priority of its upcoming presidency in the field of health and safety at work and that it expected a legislative proposal from the Commission. In May 2016, the Dutch Presidency held a major conference in Amsterdam, intensifying dialogue on this issue and giving unprecedented political visibility to the fight against occupational cancers in Europe.

For its part, the European Parliament was not going to be side-lined. On several occasions it expressed its wish for the directive to be revised, in particular extending its scope to cover reprotoxic substances. In a resolution adopted in November 2015, the Parliament “highlights the importance of protecting workers against exposure to carcinogens, mutagens and substances that are toxic to reproduction; stresses, in this context, that women are often exposed to a cocktail of substances, which can increase health risks, including to the viability of their offspring; firmly reiterates its call on the Commission to present a proposal for a revision of Directive 2004/37/EC on the basis of scientific evidence adding more binding occupational exposure limit values where necessary and to develop an assessment system in cooperation with the Advisory Committee on Safety and Health at Work that is based on clear and explicit criteria; believes that possible regulatory overlaps resulting in unintended non-compliance should be addressed in this context”.

Even the employers were divided between supporting the Commission’s deregulatory approach and the finding that the legislative standstill had unforeseen disadvantages. Politics hates a vacuum. The lack of action at the level of EU legislation on occupational health ended up with action being taken elsewhere. Very soon, national legislation attempted to fill the gaps left at EU level, and the business world soon found itself confronted with 28 sets of very different national regulations – one of the disadvantages of having very divergent national OELs. Very soon, other EU legislation had to jump in to fill the gaps. For instance, with regard to the fight against occupational cancers and with

no progress made in upgrading the rules protecting workers, marketing authorisation rules sought – somehow – to respond to the growing concerns. The synergies mentioned everywhere in the declarations of Commission leaders were nothing more than the jumpstart lurchings of a vehicle forced to start while all others remained broken down.

On 25 February 2015, a broad coalition of 21 employer organisations sent a letter to the European Commission. While upholding its ideological support for the principle behind ‘Better regulation’, the letter called on the Commission to clear the way for a revision of the CMD. It was signed by associations from a wide range of sectors: automotive, medical technology, steelmaking, mining, aluminium. etc. It was also backed by the powerful American Chamber of Commerce in Europe, an organisation representing US multinationals. While the letter was obviously not written for the sake of protecting workers’ health, its signatories expressed their concern about the legislative standstill, stating that it could lead to bans or restrictions in the context of REACH. In the view of these employer organisations, the defence of their own interests was leading them to break with the purely deregulatory ideology of their umbrella organisation, BusinessEurope.

Similarly at national level, employer organisations in several countries considered the major disparities between the various national regulations to be a problem. It was this that explained the very firm position of the Dutch employer organisation in favour of revising the directive. On 28 August 2003, the Dutch Minister of Social Affairs and Employment sent a letter to the European Commission calling on it to include the revision of the CMD in the new EU strategy for 2013-2020. The letter reflected a joint position adopted at a tripartite meeting between the Dutch government, employer organisations and unions, highlighting the large differences between Member States’ levels of protection and pointing out that more, and stricter, exposure limits at EU level would help create a ‘level playing field’ and so avoid ‘false competition’⁴.

The evolution of the Commission’s attitude and its internal contradictions are worthy of a detailed examination. However, this would go beyond the bounds of this paper. We will limit ourselves to highlighting a few hypotheses which need to be looked at in greater depth.

Within the EU’s institutional system, the Commission has one key power, that of being the only institution able to take legislative initiative; i.e. neither the Parliament nor the Council can trigger a legislative process. What they can do is to adopt resolutions, exert political pressure and urge the Commission to take action. Official positions of the European Commission are defined collectively by all Commissioners. In practice however, the Commission president and secretary-general play an often-decisive role when it comes to policy choices. In addition, each commissioner at the head of a directorate-general (DG) exerts a varying influence over overall policy. The internal balance of power is complex and fluctuates. Any political initiative (whether legislative or not) is preceded by an inter-DG consultation, allowing all DGs to have their say.

4. Letter from the Dutch Minister of Social Affairs and Employment, L.F. Asscher, to European Commissioner L. Andor, 28 August 2013.

The sometimes surprising evolution of Commission policy on the revision of the CMD is linked to a range of factors exerting contradictory pressure from outside as well as internal conflicts within the Commission. The legislative standstill was given added impetus by an overall ideological approach under which occupational health legislation was considered a burden for companies, and by the effectiveness of industry lobbying which generally targeted specific areas potentially to be covered by the revision (for example crystalline silica, diesel engine exhaust emissions or wood dust)⁵.

Different phases could thus be distinguished in which occupational health policies were overruled by other considerations. Up to 2007, the revision of the CMD seemed to be gaining ground. Though progress was slow, the various preparatory steps (including the two-stage consultation of the social partners) took place.

This momentum was stopped in its tracks by the ‘Better regulation’ campaign, which significantly reduced the say of the ‘Social Affairs’ DG within the Commission. The extreme concentration of decision-making power between the hands of Mr Barroso, the Commission President, Mr Verheugen, the Commissioner for Enterprise (in the first Barroso Commission between 2004 and 2009) and the secretariat-general played an important role in the stalemate over the revision. But this was not just a balance of power issue. It also involved – with a certain share of autonomy – the administrative procedures and the legal framework establishing new bureaucratic mechanisms for assessing the impact of the legislative proposals. Though these mechanisms are supposed to ‘depoliticise’ the legislative process, they in fact make it a lot more arbitrary. Indeed, the criteria for assessing the potential impact of any draft legislation involve studies based mainly on hypothetical projections of costs and benefits on the basis of very fragmentary data. The factors of uncertainty are of such a magnitude that all that is needed was to modify the models on which the projections are based in order to arrive at diametrically opposite conclusions. In addition, throughout the process entrusted to external consultants, the Commission remains in contact with them and may suggest introducing modifications into their studies. This influence is all the more effective as consultants are commercial organizations that want to maintain a favourable position in this lucrative market for impact evaluations. Such a decision-making system is based on a paradox: it is supposed to give priority to expert reports focused on economic impacts. This however minimises the role of expert reports on substantive issues (in this case, toxicological, epidemiological and technological data) and avoids explicitly detailing the policy choices made (for example, the determination of a level of risk considered to be ‘tolerable’ for workers which is linked to the adoption of the limit values).

The U-turn of DG Social Affairs took place towards the end of 2015. In a letter sent on 14 December 2015 to Belgian unions, Commissioner Marianne Thyssen made a series of commitments, stating that she intended to submit two proposals for revising the directive in the course of 2016 and to achieve the goal of 50 OELs by 2020. However, she reaffirmed the position that the legislative proposals could not be drafted before the end of the assessment of existing legislation. The document concerning this assessment

5. These lobbying activities are described in Tansey (2016).

was announced for the beginning of 2016. There was an obvious contradiction here: if the results of the assessment were indispensable for putting forward a legislative initiative, how could one justify the commitment of defining OELs for 50 substances? This shows at what point the formalism and bureaucratisation of EU decision-making caused by ‘Better regulation’ can become a kind of ritual where form take precedence over content.

In reality, the Communication from the Commission concerning the assessment of existing legislation was only adopted on 10 January 2017 (European Commission 2017a). But this 1-year delay has had no consequences for the revision of the CMD. It was launched more than six months before this communication, since 2013 touted as the starting point for any legislative initiative respecting the sacrosanct REFIT principles. The timetable announced in the letter of 14 December 2015 was basically respected, with a first proposal adopted by the Commission on 13 May 2016 and a second on 10 January 2017. Respecting the commitment to adopt 50 OELs by 2020 seems however to be a bit of a problem. Taking into account the first three batches, there should be between 21 and 23 OELs adopted by 2020. Assuming that the fourth batch is adopted by the end of 2020, it is likely to be around 25 OELs, about half of the stated target. For the future, there are many uncertainties since the Commission has not yet published a medium- and long-term plan for the substances to be considered for further legislative developments.

How can this change of heart be explained? Between 2007 and 2015, revision of the CMD was constantly hit by “deadline slippage”, while at the same time other factors developed, the main one of which was the entry into force of REACH (on 1 June 2007). Slowly but surely, the position of DG Enterprise (renamed DG Grow in 2015) was to change. This DG had always maintained close links with industry and was rather hostile to any developments in EU legislation in the field of health and safety, considered to be a burden weighing down on competitiveness and held to be relatively ineffective. The arrival of REACH changed this perception. For many companies, occupational health legislation seemed the ‘lesser evil’ compared to the new authorisation procedures under REACH, leading to a decrease in resistance to the revision of the directive on carcinogens. The revision gained a kind of new legitimacy in the debates on the risk management measures to be adopted for substances of very high concern.

Moreover, through accelerating the production of data on the most dangerous substances, REACH revealed the major gap between the level of protection introduced by the directive and the actual technical possibilities for improving prevention. The bulk of the data gathered during the implementation of REACH indicates that the adoption of OELs ensuring a high level of protection for workers would not come up against any major technological and economic obstacles – contrary to the claims of BusinessEurope. In fact, there was a great distance between the latter’s perception – marked by its deregulatory ideology – and the data provided by the companies concerned. This gap explains to a certain extent the quasi-inversion of roles between DG Enterprise and DG Social Affairs in their approach to regulating the occupational risks associated with chemicals. Traditionally, the former was hostile to such regulation, while the latter was more favourable to it. The current situation is less clear.

Among the substances helping to crystallise the internal discussions in DG Enterprise, we find NMP (N-Methyl-2-pyrrolidone), a substance for which the Netherlands proposed a restriction in 2012, and the main compounds of hexavalent chromium placed on the list of candidates for authorization as from 2010 and subject to the authorization procedure since 2013. In these two cases, it would seem that the measures planned in the specific legislative measures for protecting workers were clearly inadequate compared to those proposed under REACH. The reticence of DG Social Affairs to extend the CMD's scope to reprotoxic substances also seemed unjustified in the light of the fact that both DG Grow and DG Environment considered – quite rightly – that EU legislation was inconsistent. It should also be mentioned here that, in the field of social policies, the near standstill in other areas (mainly regarding the Posted Workers' Directive), in some ways created the need to launch initiatives seen to be less conflict-laden among Member States. Leaving aside automatic UK hostility towards any legislation on workers' rights, it was clear that the revision of the CMD would not face any particularly negative reactions from Member States. Quite the contrary, many of them considered it a priority.

3. The main issues at stake in the revision of the CMD

For practical reasons associated mainly with the bureaucratic impact assessment rituals, the directive is being revised in several phases (batches). This multi-phase approach is not *per se* a problem, especially as it is accepted that a directive effective in fighting occupational cancers needs to be regularly revised to take account of the latest findings. But a series of *ad hoc* revisions targeting specific points risks putting a comprehensive analysis of all prevention needs on the back burner. This is the reason why the European Trade Union Confederation is calling for the adoption of a strategic roadmap defining for the medium term these various needs and setting down an exact timetable for the various legislative measures planned.

The multi-phase approach entails overlapping debates to the extent that the legislative process associated with each batch of proposals can extend over quite a long period and will not be completed when the subsequent batch is submitted to the European Parliament and the Council of Ministers. For instance, the first batch of proposals was presented in May 2016 and ended with the adoption of a directive in December 2017. In the meantime, the second batch was introduced in January 2017, with European Parliament amendments to the proposals being voted on in March 2018 and with the negotiations between the Parliament and the Council to adopt a directive set to end in the second half of 2018. We are seeing the same overlapping with regard to the third batch, presented in April 2018 and set to be adopted in early 2019, while the fourth batch will probably be launched after the European elections in May 2019.

As a strictly chronological narrative would not take account of the vagaries of the revision procedure, we have decided to successively examine the content of each batch of proposals. As a reminder, the revision of the directive on carcinogens is taking place in the context of what is called the ordinary legislative procedure. It is up to the Commission to launch the initiative by adopting a proposal for a directive. This proposal is then submitted to the European Parliament which can adopt it as such,

amend it or reject it. It is then submitted to the Council of Ministers which has the same competences in its function as co-legislator. The directive is not finally adopted until both Parliament and Council agree on the text. This process can take place in several steps if Parliament and Council cannot agree on a joint position at the first step. The Commission continues to play an active role throughout the process. First, it maintains contact with the co-legislators and takes part in any meetings held by the two institutions for negotiating a possible agreement (the so-called ‘trilogue’). Second, it can interrupt the legislative process at any time through withdrawing its proposal. In the case of the CMD revision, this threat has been informally voiced in response to amendments deemed by the Commission to be overambitious, though it is unlikely that it will actually come about, as this would cause a great amount of tension between the Commission and both Parliament and the Council.

An inter-institutional agreement between the European Parliament, the Council and the Commission was reached on 13 April 2016. Its text is quite ambiguous, addressing the contradiction between the democratic necessity to be able to amend legislative proposals put forward by the Commission and the bureaucratic requirement to provide impact assessments of the finally adopted texts. It is highly unlikely that the Commission’s initial impact assessment will have addressed all policy alternatives arising in the course of the legislative process. With regard to both the European Parliament and the Council, an amendment is adopted when it gains a majority of votes, in line with Treaty rules. It is thus a political decision, the legitimacy of which is based on universal suffrage in the case of the European Parliament and on the sovereign representation of each Member State in the case of the Council. The agreement of 13 April 2016 states: “The European Parliament and the Council will, when they consider this to be appropriate and necessary for the legislative process, carry out impact assessments in relation to their substantial amendments to the Commission’s proposal. The European Parliament and the Council will, as a general rule, take the Commission’s impact assessment as the starting point for their further work. The definition of a ‘substantial’ amendment should be for the respective Institution to determine. This texts thus accords a major margin of discretion to the two institutions. They weigh up the substantial character of an amendment and then decide whether it is appropriate to go ahead with an impact analysis”.

At the time of writing this paper, three batches of proposals for revising the CMD had already been tabled by the Commission and a certain amount of information on the fourth batch was already available. On the other hand, the information available on the possible inclusion of reprotoxic substances is too fragmentary to predict what the Commission’s position will be at the end of the first quarter of 2019. All we know is that different scenarios are being considered.

4. The first batch of proposals: a minimalist approach, greatly improved thanks to the European Parliament

The first batch of proposals for revising the CMD was adopted by the Commission on 13 May 2016. The content was minimalist, not making any amendments to any articles of the existing directive. Its scope was thus not extended to reprotoxic substances. The amendments proposed only referred to Annex I defining the binding OELs and to Annex III containing the list thereof.

As regarded Annex III, the proposal targeted 13 substances. For 2 substances, the amendment involved the revision of existing OELs, while new OELs were introduced for the other 11.

The Commission was convinced that any proposal, however modest, would be approved without substantial amendments by the co-legislators and that its adoption would not involve any major political debates. This turned out not to be the case. It was foiled by the European Parliament's desire to adopt a far more ambitious text on a key issue causing immense social inequalities in health and the leading cause of death associated with working conditions in Europe. The Parliament's Social Affairs Committee appointed the Swedish Socialist MEP Marita Ulvskog as rapporteur. Similarly, each parliamentary group appointed a 'shadow-rapporteur' tasked with monitoring progress. During the first meetings devoted to examining the proposal, MEPs from most of the political groups grasped the importance of the subject and worked to find a consensus on amendments significantly improving the initial proposal.

On 28 February 2017, the Social Affairs Committee approved the report and adopted the various amendments on which broad consensus had been reached. This was all the more noteworthy, given that employer lobbying had done everything to weaken the rapporteur's position. No fewer than 9 European employer organisations⁶ had sent a letter to the various parliamentary groups on 4 January 2017, calling on them to stick to the Commission's minimalist approach. This letter was quick to set forth manifestly untrue counter-claims, in particular stating that the "CMD was originally specifically designed to deal with those carcinogens and mutagens without sound levels of exposure". Although the amendments were ambitious, some 85% of MEPs voted for them. Only two parliamentary groups rejected them: the European Conservatives and Reformists (ECR), a Eurosceptic right-wing group centred around the British conservatives and the Polish Law and Justice Party (PiS), and the extreme right-wing Europe of Nations and Freedom (ENF) centred around the French National Front, the Austrian FPÖ and the Italian Lega Nord. This large majority tipped the balance of power in favour of the European Parliament. The high degree of support for the amendments surprised the Commission which had attempted to portray the Parliament's position as unreasonable

6. The organisations (and their sectors) which signed this letter: Business Europe, CEEMET (metal engineering), CEMBUREAU (cement), ECFIA (insulation wool), Euro-Commerce (distribution), Eurométaux (metalworking), FIEC (construction), IMA-Europe (minerals, particularly active in lobbying for crystalline silica) and the UEAPME (for the SME sector). It should be noted that the CEFIC, the organisation representing chemical sector employers, had nothing to do with this initiative.

and maximalist. It even went as far as stating that the amendments endangered the whole revision of the directive.

The following step was more difficult, as it involved reaching agreement between the Parliament and the Council of Ministers. These negotiations took place mainly between March and June 2017. In the ‘trilogue’ procedures, the Council is represented solely by the State holding the 6-month Council Presidency, in this case Malta. This Presidency has to act within a mandate defined on the basis of an agreement between the various Member States, i.e. parallel negotiations take place in the background.

Within the Committee of Permanent Representatives (COREPER), the Member States discuss the proposal and any amendments, while the Council Presidency negotiates with the representatives of Parliament in the ‘trilogue’. The parliamentary delegation was led by the rapporteur, though all political groups took part in the meetings via their ‘shadow-rapporteurs’. Member States were basically divided into three blocs⁷. A significant group of States was in favour of supporting a major part of the Parliament’s amendments. The States most active in this group were Sweden, France, Germany and Belgium, though, in certain questions, up to a dozen States could be involved. Two States (the United Kingdom and Poland) wanted to uphold the Commission’s minimalist proposals and rejected all of the Parliament’s substantial amendments. They were very often supported by Romania and Finland. The other States took middle-of-the-road positions or did not voice a clear opinion. There was thus no clear majority within the Council⁸. The mandate given to the Maltese Presidency made negotiations very difficult. It basically supported the Commission’s initial proposals without making a specific compromise proposal including the Parliament’s amendments. No substantial amendment made by the European Parliament was accepted by the Council and the Commission showed clear hostility towards the Parliament, making any compromise even more difficult. After three meetings without a result, a final meeting (under the Maltese Presidency which ended on 30 June) was held on 27 June, resulting in a compromise proposal which received COREPER support on 11 July 2017. Overall, this compromise represented an important success for the Parliament and for the group of Member States wishing to adopt more ambitious legislation.

The compromise allowed for the adoption of Directive 2017/2398 of 12 December 2017. This directive will have to be transposed by the Member States no later than 17 January 2020. Its provisions are minimum requirements. Transposition should make it possible to adopt at national level provisions ensuring better prevention of occupational cancers.

On four important points, it is indisputable that this compromise is a major step in the right direction (reprotoxic substances, health screening, OELs for hardwood dust and hexavalent chromium). But no real progress was achieved in crystalline silica, meaning

7. These blocs were not static, i.e. their composition changed over time. Depending on the issue in question, certain States could hold more or less favourable positions regarding the Parliament’s amendments. For instance, the amendment on hexavalent chromium benefited from greater support than that on reprotoxic substances.

8. A qualified majority in the Council needs 55% of Member States, representing at least 65% of the EU population. A blocking minority must include at least four Council members representing more than 35% of the EU population.

that we will have to maintain pressure to get its OEL revised in the near future, thereby preventing thousands of deaths.

Table 1 Summary of the most important amendments discussed

Initial Commission proposal	Amendment proposed by the Parliament	Final compromise between Parliament and Council
No inclusion of reprotoxic substances within the directive' scope	Inclusion of reprotoxic substances within the directive' scope	A new (legally binding) article is inserted into the directive, requiring the Commission to consider the possible inclusion of reprotoxic substances into the directive's scope by Q1 2019 at the latest
No screening of workers' health after the end of exposure to carcinogens and mutagens	Health screening in accordance with conditions to be set by Member States	Health screening in accordance with conditions to be set by Member States and/ or prevention agencies
OEL of 25 micrograms/m ³ for hexavalent chromium	OEL of 1 microgram/m ³ for hexavalent chromium	OEL of 5 micrograms/m ³ for hexavalent chromium after a 10-year transition period
OEL of 100 micrograms/m ³ for crystalline silica	OEL of 50 micrograms/m ³ for crystalline silica at the end of a 10-year transition period	OEL of 100 micrograms/m ³ for crystalline silica, but the Commission should consider a reduction when compiling the next report on the directive's application
OEL of 3 mg/m ³ for hardwood dust	OEL of 2 mg/m ³ for hardwood dust	OEL of 2 mg/m ³ for hardwood dust at the end of a 5-year transition period

5. The second batch of proposals: exclusion of diesel engine exhaust emissions

On 11 January 2017, the Commission adopted a proposal for the revision defining the second batch of amendments to the directive. Its scope is even narrower than the first. Although the Commission initially announced that 25 (new or revised) OELs would be proposed in the course of 2016, this second batch refers only to 5, making up a total of 18 OELs in the first two batches.

The approach is again minimalist. The main point at issue in this second batch of proposals concerns diesel engine exhaust emissions. In its preparatory work, the Commission considered including these emissions in Annex I of the directive and defining an OEL in Annex III, thereby opening the door for a more systematic prevention of carcinogenic exposure. This was the main issue at stake in this second batch of proposals, given the number of exposed workers in the European Union (more than 3 million) and the number of cancer deaths caused by this occupational exposure. In the impact assessment presented by the Commission for this second batch, it estimated that 230,000 deaths would occur over the next 60 years without a legislative initiative. This is a very much underestimated figure given that it is based solely on lung cancer deaths. When taking into account the other harmful effects of diesel engine exhaust emissions, the number of avoidable deaths is much higher. The same impact assessment is not very transparent in its argumentation justifying the Commission's backtracking, presenting it as a provisional decision open to re-examination. However, the documents adopted

at a later date by the Commission seem to indicate that it is not intending to take any further initiative in either the 3rd or 4th batch of revision proposals (i.e. within the term of office of the current Commission). Two complementary lines of argumentation were formulated. In its impact assessment, the Commission puts forward a legal argument which in our view is completely illogical. It states that it would be difficult to find a satisfactory legal wording able to distinguish between emissions from new engines and those of older engines. However, such a distinction is irrelevant in the context of the CMD. In practice, workers are exposed to diesel engines corresponding to extremely variable construction standards. The composition of emissions from such engines are not dependent solely on construction standards, but also on a number of other factors such as maintenance, filter systems, combustion temperature, etc. Moreover, for diesel engines used in machines and not vehicles, the latest norms do not apply. The objective of the directive is not to define specific rules on the design of diesel engines, their possible replacement or other measures determined by market rules. The directive needs just to be based on the scientific finding that diesel engine exhaust emissions are carcinogenic. This is the conclusion reached by the International Agency for Research on Cancer (IARC) and recently confirmed by the French Agency for Food, Environmental and Occupational Health Safety (ANSES). Industry lobbying follows a more conventional strategy, sowing doubt through calling for new epidemiological studies. If account is taken of the latency period between occupational exposure and the outbreak of cancer, it is not very likely that we will have any epidemiological studies focused exclusively on workers exposed to the emissions of diesel engines corresponding to the latest norms for the next thirty or forty years. With regard to this issue, the statement of the Scientific Committee on Occupational Exposure Limits (SCOEL) that the emissions of these new technologies cannot be considered as carcinogenic is not based on consistent evidence. The only source cited in the bibliography refers to a report by the Boston-based Health Effects Institute. This refers solely to vehicles meeting the latest norms in force in the United States. The laboratory conditions of this toxicological study differ greatly from the real-life working conditions of workers exposed to diesel engine exhaust emissions in both the United States and the European Union. This report is thus not a relevant document for justifying the SCOEL's affirmation.

The issue of diesel engine exhaust emissions (DEEE) is the most important issue of the amendments adopted by the European Parliament, and will be at the centre of the “trilogue” process initiated in May 2018 under the Bulgarian Presidency and which could continue into the second half of the year under the Austrian Presidency. The Parliament's amendments were once again adopted by an overwhelming majority at the Employment and Social Affairs Committee meeting on 27 March 2018 (41 votes in favour, none against and 7 abstentions). Only two political groups, the ECR (conservative nationalists) and the ENL (extreme right) did not support the amendments resulting from a compromise between all the other groups. Claude Rolin of the European People's Party was the main rapporteur for this second batch, while Marita Ulksvog became the “shadow-rapporteur” of the Socialists and Democrats group. The convergence between these two groups has been decisive in the parliamentary work regarding the first two batches. The main amendments voted by Parliament on the second batch bring DEEE into the scope of the Directive (Annex I), setting OELs for two components of these emissions (elemental carbon and carbon dioxide) in Annex III. The Parliament

also proposes a more precise definition of polycyclic aromatic hydrocarbons (PAHs) for Annex I, the annex determining the scope of the Directive with regard to process exposures. It has also adopted a recital calling on the Commission to include occupational exposure to cytotoxic drugs within the scope of the Directive. From a perspective linking occupational health to gender equality, this amendment is of particular importance.

In the healthcare sector, many drugs have harmful consequences for staff. This is particularly the case of cytostatic substances used to treat cancers (chemotherapy). At all stages – drug preparation, treatment administration, contact with the urine or sweat of patients, waste disposal and laundry cleaning – hazardous exposures can occur if the work is not organized properly. These exposures cause cancer themselves and are reprotoxic (fertility problems, miscarriages, etc.). The staff concerned is predominantly female. While there is a serious underestimation of all occupational cancers, for women, this invisibility is particularly high. Many stereotypes associate cancers with male jobs in traditional industries, a bias also noticeable in the revision of the directive. The majority of the substances considered by the European Commission concern male jobs. This is why the amendment concerning cytostatic drugs would contribute to a better prevention of occupational cancers in highly feminized professions.

6. The third and fourth batches of proposals

The Commission adopted its proposal for the third batch on 5 April 2018 (European Commission 2018). Its content is limited to five substances or groups of substances (cadmium and its inorganic compounds, beryllium and its inorganic compounds, arsenic acid, formaldehyde and MOCA). It reflects the compromises negotiated within the Advisory Committee for Health and Safety with respect to these substances. This text is unlikely to cause much controversy, although some employers' organizations may question the proposed OEL for cadmium and its inorganic compounds. The employer's position is, however, fragile from a legal point of view. It advocates the adoption of a biological limit value, in the knowledge that the CMD does not currently allow for the adoption of binding biological limit values. The European Parliament will adopt its amendments on the third batch in November 2018.

It is too early to know what will be the precise content of the fourth batch. It seems accepted that OELs will be proposed for nickel and its compounds as well as for acrylonitrile, and that the OEL for benzene should be revised. Diesel engine exhaust emissions should also be included in the fourth batch if the Parliament's amendments to the second batch are rejected by the Council.

In fact, the most important legislative debate for 2019 will not concern the fourth batch. It will focus on the regulation of occupational risks related to reprotoxic substances. On the basis of an amendment adopted with the first batch, the Commission is required to submit an impact assessment before the end of the first quarter of 2019. Such an assessment should logically be accompanied by a legislative proposal unless the Commission rejects any change to the CMD in this area. This last hypothesis seems unlikely, especially as, within the Commission itself, several DGs (i.a. Grow and

Environment) are calling for an approach consistent with other Community legislation, i.e. setting the same set of rules for all CMRs. While the negotiations between the Parliament and the Council on the first phase led to a compromise, the Commission surprisingly launched a consultation of the trade unions and employers on 26 July 2017 under Article 154 of the Treaty on the Functioning of the European Union (TFEU). In this new document (European Commission 2017c), the Commission announces that it will not propose a new OEL for hexavalent chromium and that it will keep to the compromise negotiated between Parliament and Council in 2017 despite the high level of residual risk of this OEL. The document does not provide any explanation on how to reach the target of 50 OELs in 2020, merely listing the substances for which OELs will be proposed in the third and fourth batches. The main issue at stake in the upcoming revisions is however not the number of OELs, but concerns two subjects completely ignored in the consultation launched in July.

The inclusion of reprotoxic substances remains a key issue, but there is absolutely no mention of it in the document submitted to the social partner consultation. We will not be going into the importance of this issue as it is the subject of a specific article on page 179.

In its replies to the consultation⁹, the European Trade Union Confederation considers it essential that the European Union adopts a comprehensive strategy for eliminating occupational cancers and not one limited to ad hoc and partial adaptations focused on OELs. Although the consultation ended in December 2017, the Commission has still not adopted a communication based on the results of the consultation.

The other subject involves the way OELs are determined. The approach currently favoured by the Commission involves a cost/benefit analysis. This leads to widely varying protection levels dependent on the substance concerned. For instance, the OEL proposed by the Commission for hexavalent chromium in the first batch of proposals corresponds to a residual risk of one case of lung cancer per 10 exposed workers. Moreover, the Commission's impact assessments are biased insofar as they systematically exclude health impacts other than those related to cancer, as seen for instance in the assessments carried out for crystalline silica. Such an approach is inconsistent, as the majority of carcinogens have other harmful effects. For instance, diesel engine exhaust emissions play a major role in the development of cardiovascular diseases, crystalline silica causes respiratory diseases, beryllium is a sensitizing agent, etc. It is clear that reducing exposure to (and ultimately eliminating) carcinogens has health impacts going beyond that of preventing cancer. It would certainly lead to overall lower morbidity and mortality levels, also among those not directly exposed. A reduction in diesel engine exhaust emissions, for instance, would generally improve air quality. In our view, the cost/benefit methodology is incompatible with TFEU Article 168 which requires that "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities". This methodology also contradicts one of the fundamental principles of EU health and safety policy, according to which "improvement of workers' safety, hygiene and health at work is an

9. These documents are to be found in the book's annex.

objective which should not be subordinated to purely economic considerations”¹⁰. The Commission itself recognized the importance of this issue in 2007. In the document introducing the second stage of the consultation (2007) of the social partners on revising the CMD¹¹, the Commission wrote: “Nevertheless, scientific, technical and socio-economic data alone will not be sufficient to enable binding limit values to be set for carcinogenic, mutagenic and reprotoxic substances. What is also needed is an appropriate definition by the political authority of the level of risk that can be accepted by society. The Commission is of the opinion that these criteria for setting BOELVs¹² for carcinogenic, mutagenic and reprotoxic substances must be included in any future initiative”. Less than ten years later, against all evidence, the Commission was to state: “There were no significant divergences on the methodologies to be used and the criteria to be set up for the derivation of limit values” (European Commission 2016).

A much more consistent approach used in many Member States involves defining two risk levels: the first which, whatever the case, must never be exceeded; and the second, much lower, which constitutes the target to be achieved. The transition from the one level to the other must be ensured in two complementary ways. On the regulatory side, periodic revisions of OELs are needed to move from the first to the second level, taking account of technological progress. On the corporate side, each company must define concrete plans for minimising exposure, thereby ensuring a planned step-by-step reduction in exposure levels.

7. Conclusions

The various factors subject to the ongoing revision of the CMD were already on the agenda in 2004 when the first phase of social partner consultation was opened. The cumulative delays have had dramatic consequences, helping to aggravate social inequality in health within the European Union. The legislative moratorium adopted in 2013 has nourished the representation of the legal rules governing workers’ health and lives as an administrative burden. The current measures are nothing more than catching-up measures, allowing the CMD to be adapted to the status quo of scientific knowledge of the late 20th century and to the prevention possibilities of that time. In the meantime, new scientific knowledge is appearing, especially in the field of the causes of cancer (carcinogenesis), the role played by epigenetic processes, endocrine disruptors, the transgenerational effects of certain occupational exposures, the risk associated with the nanomaterials now finding their way onto the market, the role of multiple exposures (including interactions between exposures to chemical agents and other carcinogens), research into biomarkers reflecting physical harm to the body before a disease actually breaks out, the importance of working conditions in breaking down immune defences, etc.

10. This recital in the Framework Directive of 12 June 1989 has been acknowledged by the Court of Justice of the European Union as one of the cornerstones of Community legislation on protecting the health and safety of workers (ruling of 12 November 1998, United Kingdom vs. the Council, case C-84/94).

11. This document is available at <http://ec.europa.eu/social/BlobServlet?docId=2179&langId=en>

12. In the Commission document, this acronym stands for “Binding occupational exposure limit values”. These correspond to the OELs in CMD Annex III.

While the current legislative revision is absolutely necessary, it must not block out the need to find legislative responses to a whole range of issues related to emerging risks or to a better understanding of the problems raised. We are only at the start. There is still much work to be done. We need to create a balance of power allowing a comprehensive strategy for eliminating occupational cancers to be defined. This fight goes hand-in-hand with actions to defend the environment against chemical risks. It also has a decisive role to play if we want to combat social inequality in health. Beyond their immediate results, the current intense debates are of great importance in emphasising the political dimension of the fight against cancer.

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