Briefing for the TU Intergroup in the European Parliament on the revision of the Carcinogens & Mutagens Directive (CMD)
Summary of main issues

Introduction

More than 100.000 people die every year in the European Union due to the lack of prevention against work related cancer[1].

A precise regulatory framework is the main driver of prevention against work related cancer since most of the costs are paid by the victims and the society. In 2012, the annual societal cost of work-related cancer in the EU was estimated to be at least in an order of magnitude of € 334 billion (242 – 444)[2].

For years, trade unions and different stakeholders have urged the Commission to make proposals for a better regulation on the prevention of work related cancer[3].

In May 2016, the Commission adopted a proposal focused on setting binding occupational exposure limits (BOEL) for 13 substances (2 revised BOELs and 11 new BOELs).

The legislative process has started.

We present here the principal trade union demands which are submitted to the Council of Ministers and to the European Parliament.

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[1] *Takala J, Eliminating occupationalted cancer in Europe and globally, 2015. Download on: http://www.etui.org/fr/content/download/21462/179550/file/WP+2015-10-Eliminating+occupational+cancer+Web+version.pdf*

[2] *National Institute for Public Health and the Environment, Work related cancer in the European Union. Size, impact and options for further prevention, 2016. Download on: http://nl.sitestat.com/rivm/rivm-nl/s?link.en.documents_and_publications.scientific.reports.2016.mei.work_related_cancer_in_the_european_union_size_impact_and_options_for_further_prevention_272940.download_pdf&ns_type=pdf&ns_url=http%3A%2F%2Fwww.rivm.nl%2Fdsresource%3Fobjectid=rivmp:315353&type=org&disposition=inline&ns_nc=1*

[3] *Musu T, Vogel L and Wriedt H, Cancer risks in the workplace: better regulation, stronger protection. Download on : http://www.etui.org/fr/content/download/23435/195303/file/WP-+2016+05-cancer+risks-web+version.pdf*

1. Extension of the CMD scope to reprotoxic substances

Trade union demand:
Extension of the CMD scope to reprotoxic substances

Proposed Amendments:
Article 1(1) should read: *This Directive has as its aim the protection of workers against risks to their health and safety, including the prevention of such risks,*
arising or likely to arise from exposure to carcinogens ~~or~~, mutagens ***or reprotoxics*** *at work*

Article 2(c) **new** should read: '***reprotoxic' means: a substance or mixture which meets the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effect on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008***

Justification:
According to a recent French study[4] 1,1 % of the workforce is exposed to substances toxic for reproduction at work. At EU level, it means between 2 and 3 million workers. The CMD covers carcinogens and mutagens but not reprotoxic substances which can adversely affect human fertility and child development during gestation and after birth.
The prevention of reproductive risks in the workplace is currently too weak with the inconsistent provisions of the Pregnant workers Directive[5] (measures to avoid exposure are taken too late, i.e. after the worker informs her employer that she is pregnant while there are risks in the early weeks of gestation) and the unsatisfactory provisions of the Chemical Agents Directive[6] (OELs are indicative and there is no exposure minimization obligation below the limit value)

What are the expected benefits?
Including reprotoxic substances in the CMD scope would:
- improve workers' protection by applying the more stringent provisions of the CMD (binding OEL and minimization obligation below the OEL)
- be consistent with REACH regulation (Carcinogens, Mutagens and Reprotox considered in the same basket as Substances of very high concern)
- better protect workers from risks of endocrine disruptors (many substances that are toxic for reproduction have also been identified as endocrine disruptors)
- harmonize the way reprotox substances are regulated in the EU. Five Member States (DE, FR, AT, FI and CZ) have already extended the scope of CMD to reprotox substances when transposing the directive at national level.
  An impact study from the EU Commission[7] showed that this extension in the German and French legislation has clearly led to benefits in terms of reducing exposure of workers
- be in line with the European Parliament resolution of 15 December 2011 on the mid-term review of the EU strategy 2007-2012 on health and safety at work

[4] *Les expositions aux cancérogènes, mutagènes et reprotoxiques, INRS, Références en santé au travail, N°144,2015*
[5] *Directive 92/85/EEC*
[6] *Directive 98/24/EC*
[7] *Milieu and RPA (2012): Analysis at EU-level of health, socioeconomic and environmental impacts in connection with possible amendment to Directive 2004/37/EC. Report prepared for European Commission, DG Empl, VC/2010/0400*

More info: http://www.etui.org/Publications2/Working-Papers/Cancer-risks-in-the-workplace-better-regulation-stronger-protection

http://www.etui.org/en/Publications2/Guides/Production-and-reproduction

2. Stricter protection level on some proposed Binding Occupational Exposure Limits (BOELs) : Crystalline Silica

ETUC considers that there is a need to follow the best practice from different Member States in setting BOELs for carcinogens. Many Member States already provide a higher level of protection compared to the level proposed in the Commission proposal. This demonstrates that more protective BOELs are achievable and technically feasible for different substances in Annex 3.

Trade union demand:
Stricter binding limit value for Respirable Crystalline Silica (RCS)

Proposed Amendments:
Annex III (A) should read:

Name of agent	*EINECS*	*CAS*	*Limit values*		*Notation*	*Transitional measures*
			mg/m³	*ppm*		
Respirable Crystalline Silica(1)		14808-60-7 ; 14464-46-1 ; 15468-32-3	~~*0.1*~~ ***0,05***		-	-

(1) respirable fraction

Justification:
The proposed BOEL at 0,1 mg/m³ would expose workers to a high risk of silicosis and lung cancer. ETUC shares the view of the Scientific Committee for Occupational Exposure Limits (SCOEL) that the "OEL should lie below 0.05 mg/m³ of respirable silica dust"[8] Several EU Member States have already adopted a limit value in their national legislation lower than the 0,1 mg/m³ proposed by the EU Commission (NL at 0.075, BG at 0.07, IT-ES-FI at 0.05 mg/m³. In the US, the limit value has been recently revised and also set at 0.05 mg/m³. This demonstrates that more protective BOELs are achievable and technically feasible for RCS.

What are the expected benefits?
US-OSHA estimates that the lifetime lung cancer mortality excess risk associated with 45 years of exposure to respirable crystalline silica ranges from 11 to 54 deaths per 1,000 workers at 0.1 mg/m³ respirable crystalline silica, and 5 to 23 deaths per 1,000 workers at 0.05 mg/m³ respirable crystalline[9].

For non-malignant respiratory diseases (including silicosis) OSHA's estimate of excess lifetime mortality risk is 85 deaths per 1,000 workers at 1 mg/m³ respirable crystalline silica, and 44 deaths per 1,000 workers at 0.05 mg/m³.

[8] *SCOEL recommendation for Crystalline silica (respirable dust),SCOEL SUM/94 (2003)*
[9] *US Federal Register / Vol. 81, No. 58 / March 25, 2016 / Rules and Regulations*

US-OSHA concludes that the OEL at 0.05 mg/m³ is technologically feasible for most operations in all affected industries, although it will be a technological challenge for several affected sectors and will require the use of respirators for a limited number of job categories and tasks.

More info:
It is estimated that 5,3 million EU workers are potentially exposed to RCS, more than 70% of them in the construction sector. The main effect in human of the inhalation of respirable silica dust is silicosis. There is sufficient information to conclude that the relative lung cancer risk is increased in persons with silicosis. Therefore, preventing the onset of silicosis will also reduce the cancer risk. Since a clear threshold for silicosis development cannot be identified, any reduction of exposure will reduce the risk of silicosis and cancer.

3. Stricter protection level on some proposed Binding Occupational Exposure Limits (BOELs) : Chromium VI

Trade union demand:
Stricter binding limit value for Chromium VI compounds

Proposed Amendments:
Annex III (A) should read:

Name of agent	*EINECS*	*CAS*	*Limit values*		*Notation*	*Transitional measures*
			mg/m³	*ppm*		
Chromium VI compounds	*20-30 different compounds*	*20-30 different compounds*	~~*0.025*~~ ***0.001***		-	-

Justification:
Chromium VI compounds are non-threshold carcinogens[10]. The proposed BOEL at 0,025 mg/m³ is based on outdated data and it would expose workers to an unacceptably high excess life time lung cancer risk of 10%. According to more recent data from the European Chemical Agency (ECHA)[11] at an exposure of 0.001 mg/m³, the excess lifetime cancer risk for workers would be reduced to 0.4%. Three EU countries have recently adopted an OEL at 0.001 mg/m³(DE, FR & NL) and there is a need to follow the best practice from different Member States in setting BOELs for carcinogens.

What are the expected benefits?
A stricter BOEL is more effective in reducing exposure and therefore the number of cancer cases and deaths. According to the Commission impact assessment[12], 1670 deaths would be avoided in 2060 from occupational cancer due to Chromium VI exposure at 0.025 mg/m³. If the final BOEL adopted in the CMD is 0.001 mg/m³, the number of avoided deaths would be higher. The results of a new Commission impact study for different BOELs below 0.025mg/m³ are expected to be available soon.

More info:
It is estimated that about 1 million EU workers are exposed to Chromium VI compounds. Apart from in the chromate producing industry, occupational exposure may occur in the

[10] *Every level of exposure, however low, brings with it risks of contracting cancer*
[11] *Final report for hexavalent chromium, ECHA/2011/01-SR11, Dec 2013*
[12] *Commission Staff Working Document , SWD 2016(152) final*

production of alloys and chromium metal, production and welding of stainless steels, metal finishing processes (chromium plating) and the manufacture and use of chromium chemicals (pigments in paints, catalyst and leather tanning, etc.)
The health effects associated with occupational exposure to hexavalent chromium compounds are lung cancer but also non-malignant effects such as sensitisation, renal toxicity and irritancy and corrosivity of the skin, respiratory and gastrointestinal tract.
It should further be noted that some Chromium VI compounds are listed in Annex XIV of the REACH regulation and so are, or will be, subject to authorisation for continued use. Available evidence from ECHA[13] indicates that the vast majority of companies that have applied for authorisation can achieve an exposure level for Chromium VI compounds in the range 0.002-005 mg/m³.

4. Stricter protection level on some proposed Binding Occupational Exposure Limits (BOELs) : Wood Dust

Trade union demand:
Stricter binding limit value for Wood dust

Proposed Amendments:
Annex III (A) should read:

Name of agent	*EINECS*	*CAS*	*Limit values*		*Notation*	*Transitional measures*
			mg/m³			
~~*Hardwood dust*~~ ***Wood dust***	-	-	~~*5.0*~~*(1)* ***1.0****(1)*		-	***2 mg/m³ until (3 years after entry into force)***

(1) inhalable fraction

Justification:
Woods are customarily divided into two types: hardwood and softwood. This distinction is purely botanical and certain characteristics such as the density and hardness of the two types are largely superimposed[14]. "Wood dust" should therefore be used instead of "Hardwood dust" As the current limit value in the majority of EU countries is 2 mg/m³ or below a transition period of 3 years at 2 mg/m³ is needed to allow companies to meet the French BOEL at 1 mg/m³ which is currently the best practice in the EU.

What are the expected benefits?
The Commission impact assessment states that a BOEL at 1 mg/m³ is more costly for firms to implement but it would be more effective compared to a BOEL at 3 mg/m³ in reducing occupational exposure to wood dust[15]. The BOEL at 1 mg/m³ also leads to the highest reduction of estimated health costs.

More info:
Wood dust is a process-generated substance. It occurs mainly in the wood working industry, furniture manufacturing and construction sectors. It is estimated that 3.3 million

[13] *http://www.echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list*
[14] *Recommendation from the Scientific Committee on Occupational Exposure Limits for wood dust, Sum(102)Dec 2003*
[15] *Commission Staff Working Document , SWD 2016(152) final*

EU workers are potentially exposed to wood dust in over 340 000 companies. Exposure to wood dust is associated with an increase of sino-nasal cancers and non-malignant effect such as impairment of respiratory function and increased prevalence of pulmonary symptoms. The current BOEL for wood-dust in the CMD is 5 mg/m³ and the Commission proposal is to lower it to 3 mg/m³.

5. Stricter protection level on some proposed Binding Occupational Exposure Limits (BOELs) : Refractory Ceramic Fibers

Trade union demand:
Stricter binding limit value for Refractory Ceramic Fibres (RCF)

Proposed Amendments:
Annex III (A) should read:

Name of agent	*EINECS*	*CAS*	*Limit values*		*Notation*	*Transitional measures*
			fibre/ml			
Refractory Ceramic Fibres		*142844-00-6*	~~*0.3*~~ ***0.1***		-	-

Justification:
Aluminosilicate fibres exhibit a carcinogenic potency comparable to asbestos according to the German Federal Institute for Occupational Safety and Health[16]. A binding OEL at 0.1 fibre/ml corresponds to an additional cancer risk of 4 per 1000 exposed workers[17]. Several EU countries have adopted an OEL at 0.1 fibre/m³ (DE, FR, NO) and there is a need to follow the best practice from different Member States in setting BOELs for carcinogens.

What are the expected benefits?
The Commission impact assessment states that a BOEL at 0.1 fibre/ml is more costly for firms to comply with but it would be more effective compared to a BOEL at 0.3 fibre/ml in reducing occupational exposure to RCFs and levelling playing field across the Union[18].

More info:
RCF are vitreous materials of variable composition and properties used for insulation at high temperatures. It is estimated that 10 000 EU workers are potentially exposed to RCF. While RCF are only manufactured in three EU countries (DE, FR, UK) most exposed workers are employed in the downstream user industry across the EU. Occupational exposure to RCFs is associated with adverse respiratory effects as well as skin and eye irritation and they may cause cancer by inhalation. According to the SCOEL, RCFs are Genotoxic carcinogens for which a practical threshold at 0.3 fibre/ml is supported[19]. It should also be noted that RCFs are identified as Substances of very high concern under REACH and they are recommended by ECHA to be included in the REACH authorisation list.

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[16] *http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/pdf/910/910-Aluminiumsilikat-Fasern.pdf?__blob=publicationFile&v=2*

[17] *This additional cancer risks corresponds with the upper risk limits agreed in both the Netherlands and Germany*

[18] *Commission Staff Working Document , SWD 2016(152) final*

[19] *Recommendation from the Scientific Committee on Occupational Exposure Limits for* Refractory Ceramic Fibres. SCOEL/SUM/*165. September 2011*

6. Stricter protection level on some proposed Binding Occupational Exposure Limits (BOELs) : 1-3 Butadiene

Trade union demand:
Stricter binding limit value for 1,3-Butadiene

Proposed Amendments:
Annex III (A) should read:

Name of agent	*EINECS*	*CAS*	*Limit values*		*Notation*	*Transitional measures*
			mg/m³	*ppm*		
1,3-Butadiene	203-450-8	106-99-0	***1.12***	***0.5***	-	***1 ppm until (3 years after entry into force)***

Justification:
An OEL at 1 ppm is already technically feasible in most of the facilities producing or using 1.3-butadiene. However, 23 Member States have no limit value for this agent and Sweden has a BOEL at 0.5 ppm. A transition period of 3 years at 1 ppm is needed to allow companies to adapt and meet the Swedish BOEL which is currently the best practice in the EU.

What are the expected benefits?
The Commission impact assessment did not result in a clear preferred option for the BOEL to be set for 1,3-Butadiene[20]. The lower the BOEL, the less the risk for workers exposed to get cancer. All exposed EU workers should be entitled to get the same protection as in Sweden.

More info:
1,3-Butadiene is used in the manufacture of petroleum products and rubber products. It is estimated that 28 000 EU workers are potentially exposed to that chemical agent. Exposure to 1,3-Butadiene is associated with an increased risk of lymphohaematopoietic cancer, mainly lymphosarcoma. It is not possible to identify an exposure level for that chemical at which there is no risk of cancer (non-threshold carcinogen). The Commission proposal is to adopt a BOEL at 1 ppm (2.25 mg/m³).

7. Transparency on the cancer risk associated to each BOEL

Trade union demand

For each limit value adopted in the CMD Annex III, the underlying risk value should be made transparent and always communicated together with the numerical value of the BOEL. When new data are available, the risk value has to be adapted to the state of knowledge.

Proposed amendments:

[20] *Commission Staff Working Document , SWD 2016(152) final*

Annex 3 should include a new column with the risk calculated by the SCOEL for each OEL and the date of the last estimation.

Article 17 of the Directive should be modified and indicate that those technical adjustments of annex 3 shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.

Justification

For most of the carcinogens, the implementation of a limit value does not mean that there is no risk at all. For many carcinogens, there is no safe threshold (even a low exposure may cause cancer). In that case OEL are nevertheless useful if they contribute to minimize the exposure.

What are the expected benefits?

Making transparent the risk associated with each OEL would:

- Be an incentive for a more consistent approach to the setting of OELs in order to reduce progressively existing OELs to lower levels of risk
- Help companies to prioritize further minimization plan below the level of OELs taking into account the level of risk
- Help workers to understand the need for further initiatives in the elimination or reduction of the risk.

8. Workers' health surveillance mandatory pre and post retirement

Trade union demand

Workers who have been exposed to carcinogens and mutagens should be entitled to a health surveillance even after the end of the exposure and the end of their employment.

Proposed amendments:

Article 14 of the CMD should be amended in order to guarantee that workers who have been exposed to carcinogens and mutagens should be entitled to a health surveillance even after the end of the exposure and the end of their employment.

Justification

In many cases, workers exposed to carcinogens can develop a cancer years after the end of the exposure. Early detection is crucial for the efficiency of treatment and may save many lives. For instance, laryngeal cancers may be caused by different occupational exposures (asbestos, textile dust, rubber dust, polycyclic aromatic hydrocarbons, acid mists, etc...). For laryngeal cancers treated at the stage T1, the five year survival rate is about 90%. For stage T4, it is only 25%.

What are the expected benefits?

Life long medical screening of exposed workers result in lower mortality rates for some cancers (for instance, nasal cancers caused by wood dust, bladder cancer caused by

different chemicals). In all the cases, an early detection can improve the quality of life and the quality of care and treatment for cancer patients. It will also facilitate a compensation according to national law and practice.

At collective level, a better health surveillance system will contribute to the monitoring of work related cancers and help to adjust priorities in the prevention policies.

9. Regular review of CMD Annex 3

Trade union demand

Each entry in Annex III should be reviewed regularly and potential new entries should be considered. The ETUC calls for the adoption of binding OELs for at least 50 priority carcinogens.

Proposed amendments:

Article 17 of the Directive should be modified: "Before 31 December 2018, the Commission will propose an adaptation of annex 3 including at least 50 substances. After that date, the Commission will present a report every five year on the review of annex 3".

Justification

In a long term perspective, the trend of occupational exposure limits is to be reduced gradually in order to minimize the risk. The principle of a regular review of BOELs would allow to take into account new scientific data.

What are the expected benefits?

By extending the annex 3 to most of the frequent exposures and by reducing gradually the exposure levels, the level of risk will decrease. Stricter OELs are also a strong incentive for substituting because they may difficult and costly to implement. They will promote initiative in research and development for new production processes and a reduction of use of CMRs.

10. Member States mandatory reporting of exposure data

Trade union demand

Under article 6 of the directive, employers have to make available different elements of information to the competent authority when the results of the risk assessment reveals a risk. Unfortunately, the information is not used on a systematic way to organize better the prevention in each Member State. Data on exposure are lacking also at EU level. For some CMRs we don't know precisely in which activities and sectors and under which concrete conditions they are used.

Proposed amendments:

A new provision in article 6 should require Member States to collect data from companies and report back to the EU Commission in order to monitor the improvement of workers protection and identify future priorities. Such a report should be part of the five year implementation report required by article 17a of the Framework Directive (89/391/EEC).

Justification

The prevention of workplace cancer can not be organized efficiently if it is atomized company by company. Defining priorities, promoting good practice, supporting the substitution of carcinogens should be organized at different levels (sectors, countries, European Union). An efficient strategy requires good quality data about exposed workers. Those data should exist already at company level. They need to be collected in a systematic way. Multivariable analysis of the data is very helpful to understand the state of prevention, new and emerging risks and to develop specific programs adjusted to the real needs. At EU level the last systematic survey has been performed about 20 years ago (CAREX) and does not reflect adequately the present situation.

What are the expected benefits?

It will contribute :

- to organize workplace cancer prevention more systematically
- to identify needs for information and training.

It will help the different stakeholders to monitor the evolution of the situation.

11. Regular review of Annex 1

Trade union demand:

For different process generated substances, it may be difficult to derive a BOEL because they are a mixture of different agents. In order to improve the protection of workers, this should not prevent the inclusion of those carcinogens in Annex I to bring those substances in the scope of the CMD[21].

Proposed amendments:

A new provision should be added in article 17 of the directive. “Before 31 December 2018, the Commission will propose an adaptation of annex 1 including at least 20 process generated substances. After that date, the Commission will present a report every five year on the review of annex 1”.

[21] *Two recent lists of processes are available. The Dutch Institute for Public Health and Environment has selected a list of 20 prevalent processes (see page 24 in http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2015/juni/Identifying_prevalent_carcinogens_at_the_workplace_in_Europe :). The European Trade Union Institute has published a list where several processes are included: http://www.etui.org/content/download/22577/188583/file/Carcinogens%2C+binding+limits+workers%27+exposure+Wriedt+R+136+Web+version+2016.pdf*

Justification:

The scope of application of the directive has been defined in a flexible way for classified substances and for mixtures (substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen or mutagen).

For processes, such a flexibility does not exist. The process has to be included in Annex 1.

The present list of processes in Annex 1 covers only a minority of situations where workers are exposed to processes or mixtures which may cause cancer. For instance, rubber dust, rubber fumes, leather dust are not included.

The list of annex 1 must be updated in order to include a majority of exposed workers.

What are the expected benefits?

The experience shows that the prevention of cancer is more difficult in process generated exposures. By extending the annex 1, the prevention will become more systematic and more efficient.

12. A roadmap to stop cancer at work

Trade union demand:

The Commission should adopt a roadmap to stop cancer at work and integrate it in the EU strategic framework for health and safety at work. In particular:

a) An EU methodology has to be defined for deriving BOELs for CMRs.

b) Substitution is at the top of the hierarchy requirements and prevention measures in the CMD. Tools and instruments should be developed at EU level in cooperation with the Bilbao Agency.

c) There is a need to review other existing directives to better prevent occupational cancers. In particular, there is a need to review the asbestos directive 2009/148/EC and the optical radiation directive 2006/25/EC.

Proposed amendments:

a) A new provision should be added in article 17 of the directive: **" Before 31 December 2018, the Commission has to propose regulatory criteria for setting binding OELs for CMRs**".
b) Tools for substitution do not require any legislative initiative. It should be included in the EU strategy for health and safety (which would be reviewed in 2017).
c) The BOEL for asbestos has to be reduced. Other initiatives should be implemented according to the European Parliament resolution of 14 March 2013 on asbestos related occupational health threats and prospects for abolishing all existing asbestos.
d) Natural (sun) optical radiation should be added to the scope of application of the artificial optical radiation directive 2006/25/EC

Justification:

A) The CMD still doesn't include criteria for BOEL setting while in different EU countries a methodology has been agreed. These criteria are needed for consistency in deriving minimum requirement limit values across Europe. The EU scientific committee for OELs (SCOEL) would benefit from the work undertaken by national scientific committees. It would reduce the risk of duplication in the research activities.
B) There is a need for companies and workers to receive appropriate information for facilitating the substitution of CMRs. Public data bases with systematic information on substitution would be very helpful, in particular for small and medium size enterprises where the access to expertise is limited.
C) Asbestos is still a main risk due the high quantity of asbestos in building. Stricter BOELs have been defined in several Member States on the basis of new scientific data.
D) The main cancer risk from optical radiations for the workers is caused by natural radiations.

What are the expected benefits?

EU criteria will allow a better cooperation between the resources of the different Member States in the definition of BOELs for CMRs.
Millions of workers are still exposed to asbestos, mainly in the construction sector. A better prevention against asbestos risks may save many lives in the future.
Including sun radiation in the scope of application of the directive on optical radiations will contribute to prevent many work related skin cancers.

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