TRANSPOSITION IN EU MEMBER STATES OF DIRECTIVE 2010/32/EU ON THE PREVENTION OF SHARPS INJURIES IN THE HOSPITAL AND HEALTH CARE SECTOR

4th European Biosafety Summit | Warsaw, Poland

2 december 2013

SPANISH GENERAL COUNCIL OF NURSING

European Biosafety Network

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November 2013

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PART ONE.- CONSIDERATIONS ON TRANSPOSITION

I.- PRELIMINARY CONSIDERATIONS

We should start by reminding ourselves that due to the legal nature of European directives, Member States are required to achieve certain targets, leaving up to them, with varying degrees of discretion, the choice of means and pathways to achieve the desired result. Hence and more importantly, all directives impose two well-defined obligations on the recipients, i.e. on Member States: transposition into national legislation and achievement of the result pursued by the Community legislator.

All in all, it is worth reiterating that European directives are legal instruments of Community legislation, the nature of which is legally binding. We will be detailing these initial statements throughout the Report, in cases where it is necessary to address its detailed conclusions. Indeed, in each case, i.e. when approaching the transposition of each Directive, one has to analyse in detail, firstly, the obligation to transpose and secondly, the margin of discretion of Member States to achieve the desired objective.

We just have to note, again in terms of preliminary consideration, that it is settled case-law of the Court of Justice of the European Union that all margin of discretion granted to the transposition of a directive has its limits. The limit of Member State discretion when transposing a directive is always well-established, precisely because that limit is the pursued objective. In other words, when using their discretion in the transposition phase, Member States cannot avoid all or part of the compliance of its obligation to attain the objective sought by the legal instrument adopted by the Community legislator. The Court of Justice of the European Union has also established in settled case-law that Member States cannot take advantage of the transposition phase, in which they are solely responsible, to leave the Community text with no “useful effect”.

Therefore, it is worth establishing in the first place the objective pursued by Directive 2010/32/EU, and secondly, to delimit the detail of the material obligations that it contains, thus fixing the limits of discretion in the transposition process and finally, to carry out an individual assessment on the transposition performed in the

different countries to conclude on the level and degree of fulfilment of obligations by Member States.

In relation to this last point, it should be noted that this report is limited to examining transpositions in those countries for which it has the necessary documentation. This seems clear, but it is more important to note that the obligation to transpose may result in the elimination or revision of pre-existing regulations, or in the creation of a new regulatory instrument. Pre-existing regulation may be available in some cases, given that it is an early transposition of the Directive and that the pre-existing legislation has effectively fully or partly covered all of the transposition obligations.

Considering the above, the conclusions drawn for each country must always be understood taking into account these previous warnings that may limit their result. Of course, Member States are obliged to notify the EU Commission about transposing instruments. Among them must be those involving an early transposition of the Directive, i.e. those rules that already consider the compliance with the obligations addressed by the Community harmonization. The competent services of the EU Commission, responsible for monitoring transposition, should therefore have complete records of each country (see Article 3.2 of the Directive at hand). Thus, the ultimate use of this report depends on its subsequent contrast with the information available on the EU Commission on the transposition of Directive 2010/32/EU.

II.- PURPOSE OF DIRECTIVE 2010/32/EU GENERAL COMMENTS

The Council Directive 2010/32/EU of 10 May 2010 implements the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM (European Hospital and Healthcare Employers' Association) and EPSU (European Public Services Union).

It is therefore a Directive that requires preventive measures in a particular field of the protection of workers, a field in which the Community legislator has already implemented general measures with the Directives on safety and health of workers (Directive 89/391/EC, Directive 89/655/EEC) and in particular with Directive 2005/14/EC on biological risk prevention. In this report, we will not find a detailed analysis of the Community legislation on this area. However, its existence should be considered in any of the conclusions that can be drawn and, in particular, in those relating to the interpretative sources that the legislator and the Courts must take into account when implementing Directive 2010/32/EU.

Directive 2010/32/EU has its origins in the Spanish General Council of Nursing, with constant efforts towards the safety of patients and professionals, which has resulted in the communitisation of this fundamental requirement of health and safety at work applied in the hospital and health care sector.

The basis of Directive 2010/32/EU and the ability to achieve its objectives rests in the Framework Agreement. The content of this agreement is incorporated into the Directive as an Annex and signed by the European sectoral social partner organisations.

Following the approval of the aforementioned European Directive, the European Biosafety Network was launched at European level. The organization was established recently with the main objective of eliminating sharps injuries throughout the European Union, and a fundamental commitment to improve patient safety along with the safety of health and non-health workers.

The Network is open to professional, national and European institutions, representative associations, trade unions and other interested organizations committed to the elimination of sharps injuries throughout the EU territory. This goal will be achieved by promoting best practices and providing guidance and assis-

tance to Member States and the European Commission regarding the implementation of the Directive, in order to ensure the highest regulatory compliance levels and coverage for all workers and sectors involved. Among the objectives of the Network we must highlight the establishment of European level measures aimed at increasing the education and training of health and non-health workers and promoting safer practices as well as providing the necessary safety technologies.

Therefore, we can see that Community institutions, Member States and social partners agree on the aim of achieving a safer working environment through the prevention and protection against sharps injuries. As the Community Directive is adopted, we must conclude that there is also a firm belief that these objectives cannot be achieved with low-level, dispersed, partial, sectoral or geographically limited measures. Indeed, these objectives must be achieved globally within the European Union, without compromising the establishment of further criteria, principles, objectives and obligations at a state or, where appropriate, regional level, but always raising the protection level of workers and patients.

This is considered as the best way to respect the principle of subsidiarity. This judgement also enjoyed consensus between the reference social partners, as evidenced in Clause 11 of the abovementioned Framework Agreement, in which the first paragraph reads as follows:

"This agreement will be without prejudice to existing, future national and Community provisions which are more favourable to workers' protection from medical sharps' injuries."

In short, the main objective of Directive 2010/32/EU is to achieve the implementation of the abovementioned Framework Agreement, which is included as an Annex and concerns the prevention of sharps injuries in the hospital and healthcare sector, signed by the aforementioned European social partners. In our opinion this objective also requires, as an essential regulatory supplement, the establishment of penalties in the event of any breach of the obligations under this Framework Agreement.

Ultimately, a common minimum level of prevention and adequate protection of workers' health and safety tries to be ensured throughout the EU in the subjective and material field object of the Directive at hand.

III.- SUMMARY OF THE COMMUNITY MOTIVATION OF DIRECTIVE 2010/32/EU

Directive 2010/32/EU is based on Article 155, section 2 of the Treaty on the Functioning of the European Union in terms of which social partners can request that their agreements reached at European level are incorporated in a decision of the European Council.

As we have already mentioned, European sectoral social partners notified the EU Commission of their desire to negotiate the framework agreement, which was finally signed on July 17, 2009 and incorporated to the Directive as an Annex.

The need to convert the Framework Agreement into the object of a community-level harmonised obligation is justified in Recital 4 of the Directive:

"Since the objectives of the Directive, namely to achieve the safest possible working environment by preventing injuries to workers caused by all medical sharps (including needle-sticks) and protecting workers at risk in the hospital and healthcare sector, cannot be sufficiently achieved by the Member States and can therefore be better achieved at the level of the Union, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives",

In other words, the Community legislator has considered that the objective of protection of health workers included in the Framework Agreement is legitimate and could not be achieved solely with state-level measures. Hence, a communitisation of preventive obligations of protection was necessary, which, on the other hand, agrees with the general objective of improving the working conditions common to the European Social Policy.

Recital 9 of the Directive grants its provisions the nature of minimum harmonization, establishing as we have previously noted, that both Member States and the EU itself may maintain or introduce more demanding requirements for the protection of health workers regardless of the territorial level of decision.

Recital 10 of the Directive confirms that the intended harmonization of substantive law is not enough and Member States must make available to interested

parties the relevant penalty system in the event of any breach of the obligations. This penalty framework must be developed in detail and specifically defined in the Directive's instruments of transposition, as established in Article 2:

"Article 2.- Member States shall determine what penalties are applicable when national provisions enacted pursuant to this Directive are infringed. The penalties shall be effective, proportionate and dissuasive."

IV.- NATURE OF THE LEGAL INSTRUMENT OF TRANSPOSITION AND MEANS OF INCORPORATION INTO NATIONAL LEGISLATION

About the legal nature of the instrument of transposition

As is well known, Community law does not require the use of a specific legal instrument for transposing Directives, as they are characterized precisely by demanding the compliance of a result, giving Member States leeway to choose the most appropriate means and ways to achieve it, including the choice of legal form and nature of the transposition regulation.

However, this freedom of principle regarding the choice of the instrument of transposition has limits that have been defined repeatedly by the Court of Justice of the European Union (see for all, ECJ Judgment of May 23, 1985; Commission v FRG; Case 29/84, Rep. p. 1661; esp. Item 23).

If the instrument of transposition does not meet the conditions set by that particular case-law, the Directive object of incorporation into national legislation would lose its "useful effect". In other words, the pursued results would not be attained. As we have already noted on a general basis, the discretion margin granted to Member States in this field regarding the instrument of transposition has a well-defined frame by the Court of Justice of the European Union case-law, based on the requirement that the objectives of the Directive are met.

Above all, the instrument of transposition must be of general application, with effects on third parties, thus granting full legal certainty. Hence, a ministerial instruction or order is not enough. In any case, what is required is that the legal nature of the instrument of transposition grants the recipients of obligations and rights the accuracy, clarity and transparency required to know them, comply with the obligations and be able to exercise the rights they receive.

Likewise, the Luxembourg Court has consistently held that the instrument of transposition should have the same level as those it affects when amending or repealing them. Therefore, if subjects of Community harmonization are generally included in regulations under national legislation, the instrument of transposition should have the same regulatory level. In any case, the Regulation would have the

regulatory legal nature of *secundum legem*.

Finally, we want to insist on the fact that the European Court of Justice requires that subjective rights of individuals are secured by an appropriate resources system.

The European Court of Justice Judgment of May 23, 1985, in the Case 29/84, Commission vs FRG, in the context of freedom of establishment and freedom to provide services in Nursing, is very illustrative in order to understand the obligations of transposition.

The Court begins gathering the EU Commission's opinions according to which the aim of the Directive at hand (recognition of qualifications, Directive 77/452) cannot be achieved if national provisions contrary to Community obligations are not amended or completed (Item 20). A simple "administrative practice" would not provide enough legal certainty, clarity and transparency in the transposition of a Directive (Item 21).

The Court and the EU Commission do not share exactly the same opinion. In summary, the Court considers that a legislative or regulatory action for transpositions is not necessary and that the application of principles of constitutional or administrative law is sufficient. However, the Court clarifies that these principles should "ensure the full application of the Directive by the national administration" and that the right of individuals to invoke the provisions before the courts should also be guaranteed. The Community Court specifies that the latter condition is especially relevant when the provisions of the Directive grant rights to citizens of other Member States which are not familiar with the principles of national legislation used in transposition (Item 23).

From this case-law we understand that, according to the Luxembourg Court, the importance lays in the legal certainty granted by the instrument of transposition rather than in its legal form or nature. This certainty, clarity and transparency can be achieved by any legally binding instrument, including law principles that inform a certain administrative practice. Most national legislations consider general principles as a source of rights and obligations. We insist, nonetheless, that this is true as long as the binding force of the applicable principles is imposed on all sector partners, including public administrations. Thus, ensuring widespread compliance of obligations and allowing individuals the exercise of subjective rights

derived therefrom.

In order to complete the doctrine of the Court of Justice of the European Union, it has always been underlined that directives cannot be transposed by verbal orders, circulars, instructions or other instruments that do not provide the necessary legal certainty and do not have *ad extra* legal binding, because their issuers can modify them at any time and they are unknown to the recipients of obligations and rights, since they do not have to respect principles of publicity.

Both the Community Court and the competent national advisory bodies have consistently declared that the national instrument of transposition should correspond to the hierarchical level of national regulations that are used to regulate the issues under the Directive to be transposed.

Regarding the material content of the obligations of transposition, and putting aside the penalty system considerations, an issue we will discuss later, in all Member States the transposition must be carried out by a legislative or regulatory provision, since the health and safety of workers is regulated by instruments of that level in all national legislations.

Legislative regulations that regulate safety and health in the workplace exist in all Member States. Therefore, a transposition through regulatory means is possible as long as reference is made to the general and basic legislation, the regulatory rule being a specific development for the subsector in question.

For the time being, we would just need:

- A Government Regulation on risks of injuries from medical sharps, adopted in development of a Sectoral Law on safety and health of workers; or
- A Government-level Sectoral Regulation, on risks related to exposure to biological agents, incorporating the obligations of the new Directive on sharps into pre-existing legislation.

In both cases, the provisions of the Regulation must be precise and detailed enough not to leave a margin of discretion and uncertainty to the decisions that apply to it (Ministerial Orders). This way, legal uncertainty regarding its compliance and citing is avoided.

In the event that the national legislator plans to develop those Regulations

(provided they are Government rules) by means of Ministerial Orders (sectoral Ministry rule), a regulation that just makes the corresponding reference in its enacting terms enabling its development is not enough in any case. In other words, the regulation cannot give a blank check to the relevant Ministry.

In fact, the regulation is a valid rule for transposition if approved at government headquarters, with the full knowledge of all the Ministries, enough publicity and social intervention in its development process. On the other hand, a Ministerial Order can be modified and replaced at the Ministry's will, without the need to report to the Government. Although in some Member States the Ministerial Order is legally binding to all *(erga omnes)*, in order to become a valid instrument of transposition it must be enshrined and its provisions must be bound by higher level regulatory limits, i.e. legal foundations that grant it coverage and authorisation. Regulations are obviously hierarchically superior to ministerial orders.

Ultimately, the transposition cannot be done:

- Via a Ministerial Order without prior authorization in a Government Regulation or State law, since it would not be legally binding to all, or
- Via a Ministerial Order that incorporates all the Directive's provisions, but with a regulatory or legal authorization that simply makes a generic reference enabling its development via ministerial order. A margin of discretion would be granted to the competent Ministry, which would place us in a permanent legal uncertainty due to its potential arbitrary modifications.

These considerations, which may seem strict at first, are based on the characteristics of the matter to which we are referring.

Generally, provisions on safety and health in the workplace are related directly to the fundamental rights of workers regarding people's life and health protection. This direct connection to the protection of fundamental rights requires the highest possible regulatory level of provisions in order to fully protect workers from the different risks they face according to their activity. This is why Member States have always regulated this matter with particular respect for the principle of legal reserve and it is also the reason for Community institutions to have considered the safety and health protection of workers as a mandatory requirement that prevails over any other principle or objective of Community legislation.

We must add that Community Directives on the protection of workers from risks related to exposure to biological agents represent a detailed body of law that harmonises these imperative requirements of protection at a European level.

Finally, Directive 2010/32/EU is a regulation that adds a supplementary component to these warnings. The Community legislator has in fact considered it necessary to harmonize in detail and accurately a set of minimum and necessary measures for the protection of healthcare workers against the risks of infection, particularly from medical sharps. Hence, we are before a Community regulation that regulates directly and with very little discretion margin on matters affecting the health and lives of people. Therefore it requires the use of legal instruments that ensure the compliance of obligations and the exercise of rights with the highest regulatory hierarchy.

It is significant that Community institutions have chosen to elaborate a comprehensive legislation on protection in this professional sub-sector, especially at a moment in time when other service sub-sectors choose deregulation in order to gain competitiveness. This can only be explained if we consider that the protection of health and lives of people is at stake, and that those citizens affected by the risk of infection are the physicians that directly manipulate the instruments responsible of the risk. Moreover, these professionals are in permanent contact with patients and other users of the services.

It is about protecting a constitutional-level fundamental right in all Member States. Hence, the specific circumstances of this Community harmonization also require the use of national instruments of transposition for the first level in the constitutional hierarchy of each Member State.

In our opinion, from the previous considerations we understand that the transposition must be carried out by a legal or regulatory level instrument. Therefore, a more or less suitable reference procedure to a pre-existing regulatory body is not enough, nor is to carry out the incorporation by means of regulations that create legal loopholes or uncertainty, such as ministerial orders in some national legislations.

Moving on to other issues, it is clear that the nature of Community directives grants Member States complete freedom to transpose its provisions by state or regional level regulations. In other words, the principle of autonomy of Member

States is in force, which requires them to apply the constitutional provisions regulating the division of duties and, consequently, also respecting the institutional autonomy of the territories in its execution. The only limits to this freedom are, first of all, that the Directive has to be transposed so that its provisions have useful effect on the entire territory of the State, and secondly, that the necessary national control mechanism must exist in case of noncompliance by a territorial administration, without this being interpreted as state aggression to the powers granted to the territories. Indeed, only Member States are responsible for the failure to transpose.

About the transposition procedures opened by Directive 2010/32/EU

Regarding mechanisms of transposition, Directive 2010/32/EU contains an exceptional reference to the possibility for state-level social partners to ensure the achievement of their goals by means of the corresponding agreement. Due to its particular importance, it is best to transcribe Recital 11 of the Directive literally:

"11.- The Member States may entrust the social partners, at their joint request, with the implementation of this Directive, as long as they take all the steps necessary to ensure that they can at all times guarantee the results imposed by this Directive."

The enacting terms, in Article 3.1, have transmitted this exceptional formula which establishes that Member States may transpose the Directive as usual, introducing their requirements into the national legislation regulations or ensuring *"...that the social partners have introduced the necessary measures by agreement by 11 May 2013 at the latest. They shall forthwith inform the Commission thereof."*

What can be inferred from the transcribed provisions is that Member States can use this exceptional transposition mechanism, mediatised by the intervention of social partners under the following terms:

1) That social partners jointly request this procedure to comply with community obligations and that they represent all interested parties;

2) That social partners negotiate and sign the corresponding state-level agreement, in which obligations of the Directive are fully complied with;

3) That the mentioned agreement must be formalized before 11 May 2013, coinciding with the deadline for completing the transposition; and

4) Fundamentally, that Member States choosing this transposition mechanism ensure that the social partners, by means of the reached agreement, establish the necessary measures in order to achieve the desired result without affecting the useful effect of the Directive.

Ignoring the adoption formalities of the state-level agreement as a transposition mechanism, it is advisable to get to the bottom of the legal aspects of this formula, which is open to choice for Member States.

In the first place, we must point out that in such cases Member States must ensure that social partners have established the necessary mechanisms to achieve the pursued objective of protection. In addition, the mediatisation affecting the compliance with the obligation to transpose must not leave the Directive without its useful effect.

Indeed, the recipients of the obligations held in a European directive are none other than the Member States. The Community Court has stated this repeatedly, and this is precisely the reason why the provisions of Directives lack of horizontal direct effect. In other words, when two private parties are faced in a national dispute seeking to invoke a provision of a Directive, one of them invoking the protection of a subjective right or a legitimate interest, the Luxembourg Court has denied such a possibility, since the other party can never be a direct recipient of the obligations in a Directive due to its private legal identity.

This is why Article 3.1 of the Directive at hand, by establishing as a second mechanism of transposition the possibility to delegate or entrust the compliance of obligations to the social partners by agreement, it conditions the Member State who uses this procedure to ensure, with the appropriate legal instrument, that the desired result will be achieved.

Thus and secondly, we must interpret that in order to ensure compliance with the objectives of the Directive, the Member State choosing this transposition procedure must also use an instrument of mandatory nature, identical to the one it would have used in case of adopting a provision which incorporated the obligations of the Directive. As we have already noted, the instrument's binding force is dictated by the need to protect the beneficiaries of subjective rights and legitimate

interests.

More precisely, we conclude that the instrument chosen to control the social partners shall be legally binding and have regulatory status in order to fully secure not only the compliance of obligations, but also the full exercise of the rights that derive from it. It is the only way for individuals, workers and users of the sector to invoke their rights (vertical direct effect) before the corresponding body of the Judiciary, against the Administration, the only responsible for the obligations of the Directive and guarantor of its compliance.

V.- MATERIAL CONTENT OF DIRECTIVE 2010/32/EU OBLIGATIONS

It is not the purpose of this report to provide a detailed analysis of the contents of the enacting terms and the Annex to Directive 2010/32/EU. It focuses on defining its mandatory contents, in order to control transpositions in the Member States.

Directive 2010/32/EU contains five articles and an Annex that implements the Framework Agreement on prevention from sharp injuries in the hospital and health care sector, signed by the European social partners.

Above all, we must note that said Annex of the Directive must be considered as part of the enacting terms and, therefore, the obligations resulting from its content are imposed on its recipients with the same compulsory level of those obligations resulting from its enacting terms.

Both the obligations resulting from the articles as those deriving from the Annex should be synthesised. We must insist once more that the enacting terms' obligations are addressed immediately to the Member States and that the Annex's obligations, although biased by the Framework Agreement and addressed to its signatory parties, also require the responsibility of the Member States, becoming this way guarantors of its compliance vs Community institutions of control. Indeed, the legislator's intention is to achieve its effective compliance and therefore decided to incorporate the Annex to the Directive.

A.- Obligations of the Directive's enacting terms.

Article 1 of the Directive specifies its purpose, defining precisely the compulsory load and the binding force of the Framework Agreement included in the Annex.

Article 2 requires Member States to determine a penalty system for cases of non-compliance with the provisions adopted in the transposition process. These sanctions shall be fully effective, proportionate and dissuasive. Subsequently, this matter will be addressed in detail and independently in this Report.

Article 3 establishes the obligation to transpose giving Member States, as we have mentioned, two pathways or mechanisms: incorporating the obligations of the Annex directly into transposition regulations, or delegating its compliance to

social partners by conventional means, although always keeping the State authority as ultimate guarantor of its compliance. The transposition deadline is the same regardless of the chosen mechanism: 11 May 2013. Member States, just as any European directive, are required to report transposition acts to the EU Commission.

Article 4 establishes the effective date, after a period of 20 days *(vacatio legis)* following its publication in the Official Journal of the European Union, i.e. 21 June 2010.

It is important to note that from this date Member States are required to meet their transposition obligations. However, it is also wise to indicate that individuals may not be able to invoke subjective rights derived from the provisions of the Directive (vertical direct effect and justiciability) and that health authorities are not obliged by its contents (palliative direct effect) until May 11, 2013, when the period for transpositions ends. This direct effect of the Directive is produced once the complete or partial lack of transposition or the incorrect transposition is verified. The latter corroborates the timeliness of this Report.

B.- Obligations of the Directive's Annex.

The Framework Agreement contains a Preamble and various General considerations, which lack of binding force due to their expository nature. However, these Provisions can and should be taken into account in the event of a contradictory interpretation or conflict, since they dictate the object and purpose of what is agreed. On the other hand, they should serve as a guideline for Member States regarding transposition, since this part of the Framework Agreement constitutes the focal point of the Directive, i.e. its contents should be considered like the Recitals of the Directive. Therefore, all acts and texts to which the General considerations make reference, which serve as a normative source, should also be used in a teleological interpretation in case of doubt or omission.

The Framework Agreement contains eleven clauses that make up its enacting terms.

Clause 1 defines the purpose. In general, its purpose is to establish protection measures for a safer working environment in hospitals. In particular, its pur-

pose is to introduce protection measures for workers, specifically mentioning the prevention of injuries caused by medical sharps; establishing policies in risk assessment, prevention, training, information, awareness raising and monitoring; and putting in place response and follow-up procedures.

Clause 2 defines the scope. It tries to cover the widest possible spectrum of recipients of obligations and beneficiaries of rights. Thus, the measures set out in the Framework Agreement require employers of the private hospital sector and managerial authorities of the public sector to protect all workers, regardless of the labour framework under which they are hired, including the workers of potential subcontractors.

Clause 3 includes the Community legislator's own definitions of the different terms used in the Agreement. The definition of "Workers", in accordance with the definition of the scope of the Agreement, tries to cover all possibilities, including trainees, apprentices and temporary workers. The definition of "Shared workplaces" insists on the intention to cover the widest scope, demanding compliance from both the public and private sectors regardless of the nature and characteristics of the hospital or health service in question. The definition of "Employers" covers all natural and legal persons, public or private, responsible for health care. Subsequently, other concepts such as "Sharps", "Hierarchy of measures", regarding its effectiveness to eliminate risks, "Specific preventative measures", based on risk assessment, "Workers' representatives" and "Subcontractor" are defined.

Clause 4 includes a set of principles that shall be considered as interpretative guidelines in order to help the obligations aimed at employers meet the pursued objectives. In this sense, these interpretative principles constitute a remark on the provisions of the previously mentioned descriptive part of the Framework Agreement. These principles, which in turn derive from the existing Community and national regulation, are:

- Training of health workforce (1);
- Role of health and safety representatives (2);
- Duty of workers to self-control and behave according to the instructions received (4);
- Need to always assume the existence of risks and establish prevention

measures according to the hierarchy established by EU Directives (6);

- Duty of collaboration and consultation of social partners (employers and workers' representatives) on specific measures of information and training referred to in the Agreement (7);
- Need to take into account the complete national legislation and the applicable collective agreements (8);
- Obligation of awareness-raising shared by all social partners (9);
- Exegesis of key words: Planning, awareness-raising, information, training, prevention and monitoring (10); and
- Systematisation of incident reporting (11).

As we have noted, all of these principles help to address correct interpretations and to fill gaps in the transposition process, in the implementation of the Framework Agreement and in the compliance of its obligations. These principles also help to adopt the appropriate resolutions in defence of workers' rights when national courts have interpretative doubts regarding the national legislation which implements the Directive or when they have to implement the provisions of the Framework Agreement before an incomplete or incorrect transposition or simply before a complete lack of transposition.

However and despite its expository and defining nature, the importance of Clause 4 relies in that it establishes the main obligations of the Framework Agreement, which are bound by generic expressions and will be detailed in the subsequent clauses. Due to its significance, it is worth transcribing two of its sections literally:

> *"3. The employer has **a duty** to ensure the safety and health of workers in every aspect related to the work, including psychosocial factors and work organisation.*
>
> *(…)*
>
> *5. The employer shall develop an environment where workers and their representatives are participating in the development of health and safety policies and practices."*

Firstly, we must consider that the aforementioned section 3 of Clause 4 constitutes a clear, complete, precise and unconditional obligation aimed at all employers (health administration and entrepreneurs) in the health sector without exclusion, to ensure safety and health in the broadest sense for all workers in the hospital and health care sector as a whole. It is, however, a generic obligation in the sense that it allows the subsequent Clauses to deal with the detail of its specific development. The point is that, regardless of the location of the detail of the obligations, after reading this provision there can be no doubts about the mandatory nature of the Framework Agreement. In addition, the recipients of the obligation and the beneficiaries of subjective rights that derive must also remain well bound.

Following this provision of the Framework Agreement, the detail of the obligations would be the only thing left to develop in order to delimit the margin of discretion that employers and administrations hold to ensure compliance. This detail would finally give the obligations in question the necessary accuracy for their transposition and application in Member States. Likewise, this detail shall ensure both the compliance by hospital personnel and the eventual assertion of subjective rights before the national courts by workers, in case of an incomplete, incorrect or lack of transposition.

The detail of the obligations is included in Clauses 5 to 10 of the Framework Agreement. Of course, we must always bear in mind the existence of specific national and Community legislation adopted prior to the Directive at hand, which is also applicable.

Clause 5 (“Risk assessment”) contains a precise obligation that requires the existence of assessment procedures and makes reference to certain articles of pre-existing European Directives adopted in harmonisation of Community criteria on risk assessment, which have logically already been object of State transposition. At the same time, this Clause specifies the framework and criteria of assessment procedures as an obligation to achieve a result, leaving a certain margin of discretion for its application. From all this we can infer that this obligation would be infringed:

- if there is simply no risk-assessment procedure; or
- if the applied assessment procedure does not take into account the crite-

ria provided by Clause 5 of the Framework Agreement and by the provisions of the Directives referred to.

A common example to all countries and situations concerning the result of the risk assessment is that, regardless of the health centre's legal system, accidents increase exponentially in situations of stress, reduction or lack of staff, external pressures or when the work needs to be sped up. We are therefore facing a crucial issue that must be kept in mind when reflecting on health policy.

Clause 6 ("Elimination, prevention and protection") deals in detail with the material obligations that prevention, elimination and protection protocols must fulfil. It is not the purpose of this report to provide a detailed and technical analysis of reference obligations. However, we must underline that the mandatory nature of the provisions in this Clause becomes evident when the following terms are used: "must be eliminated", " specifying and implementing procedures", "eliminating the unnecessary use", "shall be banned with immediate effect", "the following measures are to be applied", "shall be offered vaccination", "shall be informed" ...

These are all expressions that clearly order the recipient of the obligation to give a full response to its requirements, which in some cases requires a specific compliance procedure. In other cases, the editors have described a range of hierarchically related options, all of which share the aim to attain the desired result and should, therefore, be achieved by implementing national-level protocols.

Ultimately, provisions of Clause 6 contain a clear, precise and unconditional definition of the obligations aimed at the health administration and entrepreneurs of the sector. Thus, the regulatory nature and compelling force of its provisions and the completeness of the obligations described only leave room to choose the means of implementation, without any doubt or legal loophole that would prevent and mediatise said compliance.

As its title suggests, Clause 7 ("Information and awareness-raising") imposes an obligation of information and awareness-raising of workers. This obligation is detailed in several specific requirements ("the employer shall"). We are again faced with a clear, precise and unconditional obligation that only requires its implementation in order to achieve compliance.

Clause 8 ("Training") imposes the obligation to provide appropriate training for workers on accident prevention, protection and elimination procedures and

protocols. Once again, this is a complete obligation that only requires implementing acts that, in addition, should consider the training measures referred to in the Clause. Hence, the training obligation is embodied in a double burden: The obligation of the employer to implement training actions and the obligation of workers to attend these courses.

Clause 9 ("Reporting") regarding accident reporting procedures also is embodied in the double aspect of revision agreed by all social partners on reporting protocols and the workers' obligation to report any accident.

No preventive measure or risk assessment will be effective unless the importance of the need to comply with the obligation to report accidents is established. The objective of the Directive cannot be achieved without the necessary information about the truly existing risks and this is the meaning of this fundamental obligation. We know that only half of the accidents that occur are reported. This is due to different reasons: professionals feel guilty about the accident; they do not understand the need to report it when the risk of infection is low; they consider the bureaucratic process of reporting a waste of time; they consider that even if the accident is reported nothing will change or they are simply not properly informed about the reporting requirement.

Clause 10 ("Response and follow-up") further emphasises the main obligation of establishing control policies and procedures and the obligation of making workers aware of the existence of these protocols. This clause specifies a set of actions that develop in detail the monitoring of control policies and that should be implemented and applied by the means established by the applicable national regulations and collective agreements. In fact, this reference to national regulations must also be interpreted as a reiteration of the generic obligation to comply with the requirements of the Framework Agreement and the previous Community regulations, by adopting legally binding instruments. This is a new delineation of the mandatory nature of the Framework Agreement, which will later result in the mandatory nature of instruments of transposition of all previously mentioned obligations.

The essence of this Clause is that the editor uses the definition of the follow-up action to further detail, if necessary, the obligations of administrations and entrepreneurs in order to achieve the appropriate protection for workers.

It is important to specify the inclusion of the provision on the obligation of rehabilitation, continuous employment and workers' compensation in this Clause. Once again, such measures shall be presented taking into account national regulations and collective agreements. An obligation requires the implementation of redress mechanisms and employment reintegration.

Clause 11 mentions the implementation of the Framework Agreement. It begins by specifying that the Framework Agreement is applied "without prejudice" to existing, future national and Community regulations. A statement that certainly seeks to consolidate the necessary existence of previous obligations resulting from applicable EC Directives and their transposition regulations, in terms of biosafety or, more generally, health and safety and risk prevention. This statement reveals its complementary nature, by no means less important, regarding pre-existing European harmonization and mandatory national regulations. Therefore, it is a complementary Framework Agreement that becomes the minimum protection framework once the Annex is incorporated to the Directive. The reference made to the future regulation could have been avoided given the necessary application of the *lex posterior derogat priori* principle.

The second paragraph of this Clause is especially relevant because the communication of the Framework Agreement is imposed to the Council of Ministers of the European Union. Its compliance has resulted in its incorporation into the Directive at hand, which is ultimately imposed on Member States.

The third paragraph of Clause 11 gives social partners who signed the Framework Agreement a particular interpretative role, upon request of the European Commission.

The Framework Agreement shall be reviewed five years after the publication of Directive 2010/32/EU, i.e. June 2015.

From the above we conclude that Clause 4 (items 3 and 5), Clause 5, Clause 6, Clause 7, Clause 8, Clause 9 and Clause 10 of the Framework Agreement contain complete, precise and unconditional obligations which may be required before the competent authorities and from which the corresponding individual rights of workers in the hospital and health care sector derive.

VI.- ABOUT THE PENALTY SYSTEM

As we have noted, the first objective of Directive 2010/32/EU is to establish protocols, criteria and measures to minimize risks. The second objective of the Directive is to require the existence of a penalty system that ensures the appropriate preventive measures. Indeed, no administrative obligation is complete if it is not subjected to coercion in cases of non-compliance or infringement.

Article 2 of Directive 2010/32/EU imposes the existence of this penalty system. Penalties in terms of occupational risk prevention, including the prevention of sharps injuries in the hospital and healthcare sector, have a double aspect: criminal for severe cases and administrative for the rest.

Such general penalty systems exist in all Member States. In theory, most of these penalties and sanctions should be in accordance with the Community mandate of the Directive at hand.

Normally, no amendment shall be required for general regulations relating to criminal law or the administrative penalty system envisaged by domestic legislations, and especially for those which refer to the regulation on occupational risk prevention. Furthermore, it is also certain that the provisions of the administrative penalty system applicable in each country and the provisions of criminal regulations meet the three Community requirements of proportionality, effectiveness and dissuasive effect, which are common principles to any penalty system in the EU territory.

However, the existence of general penalty systems is one thing, but to effectively comply with the obligation that the Directive imposes is another very different thing.

Above all, we would like to note that the Directive requires administrations and employers in the private and public sector to comply with its obligations. Therefore, in the delineation of the scope *ratione personae* of the administrative penalty system, there can be no distinction made on grounds of the public or private nature of the employer, which in any case must take the necessary measures to avoid the risk of its workers and be subject to the applicable penalty regulations in case of non-compliance.

Similarly, in relation to the scope of the penalty system, it should be noted

that criminal laws establish the possibility of imposing criminal offences and sentences both in its intentional or grossly negligent form, in case of severe risks to the physical integrity or life of workers. This is the criminal field of preventive regulations in terms of occupational risks; a regulation common to the legislation of all Member States transposing the corresponding European Directives.

Due to their clarity, it is noteworthy to reproduce articles 316 and 317 of the Spanish Criminal Law:

> Article 316:
>
> *"Those who, breaching the rules on labour risk prevention, being legally obliged, do not provide the necessary resources for the workers to carry out their activity with the appropriate health and safety measures, so that they seriously endanger their life, health or physical integrity, shall be punished with imprisonment of six months to three years and a fine from six to twelve months."*
>
> Article 317:
>
> *"When the felony to which the preceding Article refers is committed due to serious negligence, it shall be punished with the lower degree punishment."*

In any case, this relates to risk crimes, i.e. the confirmation of the existence of a specific threat to the life, physical integrity or health of a worker is enough to be guilty of a completed offence. A previous infringement of occupational risk prevention regulations is a necessary premise for its implementation.

However, in most Member States criminal law does not specify the particular infringements in terms of occupational risks that may constitute an offence. In other words, in this field criminal law tends to take shape as an abstract rule of criminal law. As a result, it is necessary to resort to the general regulation of occupational risk prevention and the different national regulations that develop it, in order to determine the type of offence committed, the penalty for it and the severity of the risk for the worker.

Moreover, the existence of causation between the omissive behaviour and the result of a specific threat or injury is necessary in this penalty field.

It is of utmost importance to note that any new penalty system shall always be established by a legal-level regulation, or at least, be fully protected and predetermined in an pre-existing Act that serves as a base. This is required by principles of legal reserve, transparency and the necessary definition of offences and penalties.

The first consequence of this is that if there is no sectoral law to protect the new penalty system set forth by the Directive at hand, the national legislator shall be forced to address its development and approval by Parliament.

This outline law could formally provide further development by regulatory means. In other words, if a sectoral law containing a general penalty system already exists, this regulation could serve as legal cover for a regulatory development and specific definition in order to comply with the Directive's obligations.

However, the specific penalty system that enforces the obligations of the Directive shall be precise and shall accurately define the infringements or improper conducts and their penalties, adjusting the latter in relation to their severity.

VII.- CONSEQUENCES OF THE LACK OF TRANSPOSITION OR INCORRECT/INCOMPLETE TRANSPOSITION. RIGHTS OF HOSPITAL AND HEALTH CARE WORKERS

1.- Verification of non-compliance of the obligation to transpose.

Without intending to dwell on this well-known issue, it is the right of any institution or natural person to report a case of non-compliance with the obligation to transpose before the EU Commission. Of course, there is also the possibility of an opening by operation of law of the corresponding non-compliance procedure by the Community institution, guardian of the Treaties. Without going into the details of the procedures (report, letter of formal notice, reasoned opinion...), the procedure may result in a CJEU conviction that the offending State must comply.

The possible existence of a CJEU conviction would obviously help to the description of the offence and therefore the liability requirement for offenders, including Member States. Similarly, a CJEU conviction in the prejudicial process that declares the incompatibility of the national legislation with the Directive, for the resolution of a pending national dispute, shall be equally valid as an element of description.

2.- Actions of workers before administrative, criminal, labour and civil jurisdiction.

- An administration (central or regional) may report or present an opening by operation of law against a health care institution (public or private) that has failed to comply with the obligations of the directive, urging the implementation of the national penalty system.
- A report may also be filed before the national administrative jurisdiction by act or default. The court decision may also rule on the corresponding compensation claim for damages based on the non-contractual liability of the offending administration.
- An administration may take disciplinary actions against the managing office or body of the offending health care institution.

- It may also bring disciplinary proceedings against the corresponding practitioner for breaching the code of ethics applicable to its professional association.
- In any case, compensation for damages before civil jurisdiction may be considered in those Member States where non-contractual liability is not a legal reality applied by the Courts and defined by law.
- A report or complaint may be filed before the criminal courts in the event of a major infringement of the regulation regarding the transposition of the Directive, on the basis of the general penalty system regulations on the protection of the safety and health of workers and the specific provisions in the scope of the Directive 2010/32/EU. This possibility relies on the assumption that the transposition is correct and complete. The proceedings and the subsequent decision may include the appropriate civil liability.
- Labour inspectors of the competent national administration are normally the ones who can open the way for the implementation of the penalty system and, in addition, a report may be filed before labour jurisdiction.

3.- Direct effect.

In case of an incorrect or incomplete transposition or a total lack of it, the report of a worker before a national court (administrative, criminal, labour or civil) may result in the implementation of the provisions of the Framework Agreement and Article 2 of the Directive at hand by the Court (*ex parte* or prior preliminary ruling of the CJEU), responding to the worker's assertion of his subjective right derived from the direct effect of one of these Community provisions:

- A national dispute may confront the worker with the health care institution or public company of the hospital or health care sector. This results in the resolution of the dispute on the basis of the Community provision, which makes up for the absence of a national provision or, depending on the supremacy of Community law, displaces the national provision incompatible with the obligations of the Framework Agreement (vertical direct effect).
- Health care workers cannot invoke the provisions of the Directive in the event of a dispute against another individual (private hospital). In this case, when a Member State fails to comply with the obligation to transpose, workers only have

to possibilities:

a) That, despite everything, the judge of the national dispute interprets national provisions allowing its implementation to be compatible with the Directive and, if such provisions do not exist, filling the legal void by means of this interpretation based on the provisions of Directive (interpretative direct effect). Indeed, the national judge is required to interpret national regulations in order to achieve the useful effect of the Framework Agreement (see ECJ Judgment of November 13, 1990 in Case Marleasing).

b) That the health care institution or private hospital applies directly the provisions of the Framework Agreement (palliative direct effect) when a Member State fails to comply with their transposition obligations.

4.- Claim of the non-contractual liability of the State.

a) In case of a correct transposition, the employee may appeal to the contentious-administrative jurisdiction for non-contractual liability of the Administration. In most national legislations that contemplate this possibility of the Administration's pecuniary liability and the victim's corresponding right to compensation, the compliance of usually restrictive conditions is required: evidence of the existence of damages, that the damages are not legitimate, the existence of a cause-effect relationship between the proceedings of the Administration and the damages, and that the injury is real and can be compensated individually in the form of money.

b) In the case of an incorrect or lack of transposition of the Directive, the non-contractual liability of the State for non-compliance of the Community law can be claimed before the contentious-administrative jurisdiction of the State, in this case for failing to comply with the obligations resulting from the Framework Agreement.

Since the well-known ECJ Judgment of November 30, 1991 in Case Bonifaci and Francovich, the non-contractual liability of Member States to compensate for damages caused by an incorrect, incomplete or lack of transposition of Directives has been incorporated into the fundamental principles of Community law. It is the cul-

mination of a European Rule of Law in which the subjects are not only the States but also their citizens. National courts must ensure the protection of the rights of European citizens, including of course the rights of workers of the hospital and health care sector in its broadest sense.

But this possibility of economic compensation by non-contractual means has several conditions:

a). That the obligation to transpose has not been complied with and, if appropriate, that the infringement has been verified by the ECJ, which will give it further characterisation, in the terminology used by the High Court.

b). That the invoked Directive has subjective rights included in its provisions and that its terms are clear, precise and unconditional. We have previously seen that this condition is met regarding the provisions included in Clauses 4 to 10 (both included) of the Framework Agreement and in Article 2 of the Directive about the penalty system. In addition, we have seen that these provisions of the Framework Agreement do not leave any margin of discretion to Member States with regard to the compliance of their obligations. Therefore, they should be limited to their implementation.

c). That causation exists between the Member State's infringement of its obligations and the damage suffered by the worker.

d). That the infringement is sufficiently characterised. This condition is met when there is a complete lack of transposition. In this case, the intentional or unintentional nature of the infringement and damage caused and the inexcusable nature of the error makes no difference. These classic requirements of the Supreme Courts' case-law in the different European countries are not taken into account to compensate the damage when it comes to an infringement by complete lack of transposition. As we have already noted, the characterization of the infringement is automatic if there is a resolution of the ECJ that verifies the failure to transpose or when, by means of a preliminary ruling, the Luxembourg Court has declared the incompatibility of a national legislation with the Directive, in our case with the provisions of the Framework Agreement.

In all these cases, the worker who invokes the Directive and the provisions of the Framework Agreement shall be compensated for damages by national court bodies.

CONCLUSIONS OF PART ONE

FIRST

The specific objective of Directive 2010/32/EU (hereinafter, the Directive) is to achieve throughout the EU and to the fullest subjective and objective extent a demanding policy on the prevention of sharps injuries in the hospital and health care sector.

SECOND

When adopting the Directive, the Community legislator wanted to make clear that the desired objectives of protection could not be achieved only with state-level measures. However, the Directive represents a minimum harmonisation that Member States can overcome for a better protection of health workers.

THIRD

The legal instrument incorporating the Directive into national legislation must be of general application, with effects on third parties, and legally binding. This legal instrument shall have the same level as those it affects and have sufficient legal certainty, clarity and transparency so that the Administration, health institutions and hospitals comply with their obligations and individuals can assert their rights. This instrument cannot give the competent authority the possibility to amend or repeal it at will, without the Government's adequate control by regulatory means.

FOURTH

The Directive can be transposed by State and/or regional regulations, as long as the whole territory is subject to its provisions.

FIFTH

Member States may transpose the Directive delegating its compliance to the

social partners by signing the corresponding national agreement. In this case, the State must ensure that the pursued result is truly achieved.

SIXTH

The obligations of the Framework Agreement, included in the Directive as an Annex, also require the responsibility of the Member States despite being aimed at the signatory parties.

SEVENTH

Once the Directive has been transposed into national legislation, both private sector employers and administrations and other public hospital and health care sector managers are required to comply with the measures of the Framework Agreement. All workers, regardless of their employment relationship, shall benefit from this protection.

EIGHTH

Clauses 4 to 10 (both included) of the Framework Agreement contain complete, precise and unconditional obligations that are imposed to the competent authorities and employers of the hospital and health care sector. The corresponding subjective rights that all workers may invoke derive from these clauses.

NINETH

The Directive requires Member States to provide a penalty system that ensures the appropriate prevention measures within the framework of occupational risks prevention. This penalty system shall be applicable in the public and private sector.

TENTH

An incorrect, incomplete or lack of transposition of the Directive shall lead to an infringement procedure, and workers and their representatives may report it to the EU Commission.

ELEVENTH

In addition to the latter, in cases of non-compliance with the obligation to transpose:

1) Member States are financially responsible for any damages caused.

2) Private sector workers may also require the liability of the offending State for the damages caused.

3) Workers of any field may invoke the provisions of the Directive before national courts in any dispute against the administration or public entities of hospital and health care management.

TWELFTH

In any case, workers can take actions before administrative, labour, criminal and civil jurisdiction in defence of their legitimate interests that derive directly from the Directive. In addition, workers may report any infringement of the Directive, the Framework Agreement and its national transposition regulations to the sanctioning authority in the field of occupational risks prevention.

PART TWO

TRANSPOSITION ANALYSIS OF DIRECTIVE 2010/32/EU IN SOME EU MEMBER STATES

PART TWO.- TRANSPOSITION ANALYSIS OF DIRECTIVE 2010/32/EU IN SOME EU MEMBER STATES

This chapter of the Report deals with a detailed analysis of the national legal instruments of transposition of Directive 2010/32/EU. As we have previously mentioned, this analysis cannot be complete for two reasons. Firstly, due to the lack of specific information about several countries and, secondly, because the possibility of an early transposition of its contents must be taken into account, which would obviously spare the need for action. Subsequently, in order to conclude if the transposition was successful, the available information of several Member States is compared with the contents of Directive 2010/32/EU, which as we have seen are legally binding.

First of all and on a general basis, we must note that throughout the EU, either of its own accord or as a consequence of the mandatory compliance of implementing EU Directives, there is a general policy on prevention of occupational risks valid for all Member States. In many cases its contents already cover the requirements of the Directive at hand, even with the corresponding incorporation of specific chapters on risks in the hospital and health care sector. Obviously, the corresponding State regulation on biosafety also exists, depending on the transposition of European Directives.

The ICF GHK Final Report, conducted on the basis of the EPSU-HOSPEEM questionnaire, funded by the European Commission and entitled "Promotion and Support of Implementation of Directive 2010/32/EU" has concluded that in most Member States an early transposition of the Directive resulted in measures of less importance and that some countries did not need additional measures to the existing regulation.

However, this should not hinder the need for a specific transposition of the Directive at hand, a national regulation that shall address in detail the incorporation of the specific obligations into national legislation. A simple reference to the pre-existing regulation is not enough when this regulation lacks precision and does not refer specifically to the prevention of risks associated with the use of sharps.

A.- SPAIN

Instrument of transposition

In Spain, at national level, the transposition was carried out by the Order of the Ministry of Employment and Social Security (ESS/1451/2013 Order of 29 July). We must note that the Order is not an adequate instrument, even if adopted in development of the Spanish Royal Decree 664/1997 of May 12 on the protection of workers from risks associated with the exposure to biological agents at work.

Therefore, the means of transposition has been the incorporation of the obligations deriving from the Community law into a specific national regulation, and not its delegation to social partners. However, as specified in the Explanatory Memorandum, the Order has received the participation of business and trade union organisations for its elaboration.

In the particular case of Spain, the incorporation of a Directive into national legislation should not be done simply by a Ministerial Order. A Royal Decree is the appropriate instrument of implementation. As the CJEU has consistently held, this is because the instrument of transposition shall have the same regulatory level than the legal system used to regulate this subject, which are regulations for Spain and most EU Member States.

In addition to this, we must take into account that in Spain, a decentralised state, the regional administration (Autonomies) had passed orders and decrees on biosafety before the approval of the Directive (Madrid, Castile–La Mancha, Balearic Islands, Galicia and Navarra). According to the conclusions of the "Comparative analysis" conducted by the General Nursing Council of Spain, autonomous regulations fit in with Directive 2010/32/EU when referring to the material content of the transposition (See the mentioned comparative study).

About the purpose

Article 1 of the Order reproduces literally the provisions of Clause 1 of the Framework Agreement and refers to the aforementioned Royal Decree 664/1997 as a basic regulation.

Therefore, it is an incorrect transposition regarding the range of the chosen

regulation, although basically a correct transposition regarding the description of the purpose of the regulation, since it has been transcribed literally. This literal transcription technique used by the Spanish legislator is not precisely the ideal legislative technique for transposing Directives. However, it could be an advantage when it comes to defining accurately the purpose of the regulation or its obligations. Nevertheless, this literal transcription must always adapt the terminology and concepts used by the Directive to the characteristics of the lexicon and the national regulation, in order to make them understandable for the competent implementing authority and the beneficiaries of the subjective rights contained therein.

Scope and definitions

Article 2 of the Order transcribes Clause 2 of the Framework Agreement, and adds a clarifying remark regarding its scope, which applies to both the public and private sector. This remark is very convenient to improve the consistency with the Community definition of "workplaces covered". In this sense, the Framework Agreement includes this remark in its definition.

The Spanish legislator continues along the lines of Act 31/1995 of 8 November on the Prevention of Occupational Risks, in which Article 14.1 provides the following:

> "1. Workers have the right to an efficient protection in terms of safety and health at work. The said right implies a corresponding obligation of employer to the protection of workers against occupational risks. This obligation of protection constitutes, equally, an obligation for the Public Administrations with regard to their employees.

The definitions coincide accurately with the ones included in the Framework Agreement, but we must point out two considerations:

- The definition of "employers" includes cooperatives and the Public Administrations, thus strengthening its application to the public sector, regardless of the legal relationship with the workers.
- The definition of "sharps" includes that this material has the consideration

of “health care product”. This is relevant in the referred national legislation, although it should be pointed out that neither the Directive nor the Framework Agreement specify the various affected safety health care products or their characteristics.

Finally, the definition of “hierarchy of measures” is omitted in the Order of transposition. In our opinion, this omission does not affect the validity of the compelling force of such measures, since the lack of this definition does not entail legal uncertainty regarding the hierarchy of measures imposed by Directives 89/391/EEC and 2000/54/EC. Evidently, these measures remain fully applicable along with their respective instruments of transposition.

Risk assessment

In particular, the Order of transposition develops the content of the information to be considered for risk assessment, thus completing the provisions of the Framework Agreement.

Elimination, prevention and protection measures

The Order develops in detail the procedures and measures for eliminating risks and it also provides a literal transcription of the contents of the Framework Agreement. In addition, it completes other provisions of the Framework Agreement on the different measures of risk elimination.

Information and awareness-raising

Literal transcription.

Training

Literal transcription.

Reporting

Literal transcription.

Response and follow-up

Complete transcription, which improves the understanding of the text.

Penalty system

The Order is just a reference to the general sanctioning regulation: Employment Infringements and Penalties Act (Spanish Royal Legislative Decree 5/2000 of 4 August).

Specifically, it is worth to reproduce Article 5.2 of the mentioned Act.

> *"Article 5:*
>
> *2. Actions or inactions of the different responsible parties, subject to liability under this Act, that do not comply with laws, regulations and normative provisions of collective agreements in terms of safety and health at work are considered employment infringements in terms of occupational risk prevention".*

Article 11 and the following of this Act specify the infringements in terms of occupational risk prevention, referring to the general regulation in this subject: Act 54/2003 of 12 December and Act 31/1995 of 8 November on the prevention of occupational risks.

It is of utmost importance to mention Article 45 of Act 31/1995 regarding the prevention of occupational risks in Public Administrations, taking into account all the implementing regulations.

Regarding the penalty system, the transposition seems inadequate and incorrect to us since the Order just makes reference to the applicable sectoral legislation. We believe that a definition should have been made, specifying the punishable infringements and the penalties for each of them. The respective chapter should have been included in the Royal Legislative Decree 5/2000, by addressing

its corresponding amendment for extension.

Indeed, the chosen formula of a simple generic reference without including the corresponding changes of the sectoral sanctioning regulation does not cover the minimum expectations of confidence and legal certainty required. In the first place, as we have previously noted, it does not define the punishable behaviours and sanctions (legal definition principle of all penalty systems). As a result, the sanctioning authority is given unacceptable margins of discretion which ultimately leave the Community obligation without useful effect. In the second place, this incorrect and inadequate formula leaves workers of the hospital and health care sector without the respective reference regulation to exercise their right to complaint with enough certainty and knowledge.

In order to establish an offence, the legal definition principle, common to all Member States and applicable to all administrative disciplinary procedures, requires that the infringement of the legal system is provided specifically in a legal-level regulation. In the case of Spain, this requirement is included word for word in Article 129.1 of Act 30/1992 of 26 November, as transcribed below:

> *"Article 129.1:*
>
> *Infringement of the legal system will be considered an administrative offence only if a law has established it as such."*

B.- FRANCE

Instrument of transposition and purpose

In France, the transposition has been carried out by a Decree that amends the Labour Code. An article that summarises the pursued objective, giving it the maximum subjective and objective extent, is incorporated into this State regulation. Decrees in France are legally binding to all *(erga omnes)*, thus granting full legal certainty for its compliance in terms of regulatory intensity. This article mentions the Order of the Ministries of Labour and Health, in which the enacting terms that cover all the obligations imposed by Directive 2010/32/EU are developed in detail.

The Order establishes clearly that it is adopted for the transposition of the Directive and includes Directive 2000/54/EC on the protection of workers from risks associated with the exposure to biological agents at work as a preceding text. Consequently, it is a specific instrument of transposition that includes the new Community obligations, by means of a legally binding regulation (the Labour Code). However, it would have been more effective if the provisions of the Ministerial Order had been incorporated into the enacting terms of the developing Decree.

Regarding the legal level of the regulation, the transposition cannot be considered formally adequate since the Decree does not specify any detailed obligation whatsoever. In addition, we do not understand the use of a Development Order of the Decree, preventing the incorporation of Community provisions into the enacting terms of the regulation. Thus, the compelling force of the Community provisions is being distorted, handing a blank check to the competent authority for the approval of development orders and amending decisions.

Scope and definitions

Article 1 of the Order contains a set of definitions whose wording and references make clear the pre-existence of sectoral regulations of a more general scope. In this case it is a correct transposition.

Article 2 of the Order opens the scope to preventive and curative actions referring to the definition of “worker” in the Labour Code. It also widens the scope

noting that the considered events may take place inside or outside the hospital.

Obligations are aimed both at public and private institutions, including medical transport services. In addition, the Order covers other institutions that are not included in the definition of public or private health institution provided by the Public Health and Family and Social Action Code.

Elimination, prevention and protection measures

Article 3 of the Order and its Annex I cover and detail the measures envisaged by the Framework Agreement, thus establishing its correct transposition and detailed implementation.

Information and awareness-raising

Article 4 of the Order and its Annex II contain a detailed transposition of the terms of the Framework Agreement. To conclude, it is an adequate transposition.

Training

Article 5 of the Order, which again refers to Annex I, covers the main provisions of the Framework Agreement concerning the training of workers. Some of the training measures are already developed in Annex II. Therefore, we are once again before a correct transposition and an implementing development.

Reporting

The reporting requirement imposed on workers is incorporated in Article 6 of the Order, along with the requirement imposed on health authorities to refer to reporting procedures, in collaboration with the involved social partners. It is therefore a correct transposition.

Response and follow-up

The basic obligations of the Directive are incorporated into Annex II of the Order, which we consider a correct transposition.

Penalty system

The penalty system has not been object of specific reference; we may consider therefore that there is a total lack of transposition. This lack of national regulations that incorporate Community provisions into the national legal system constitutes an important infringement because it leads to an evident legal uncertainty both for the recipients of obligations and for the beneficiaries of the subjective rights of the Framework Agreement.

Therefore, a formal infringement caused by a complete lack of reference to a penalty system shall be confirmed, along with a material infringement due to the absence of a specific penalty system that defines the offences and penalties related to the obligations resulting from the Directive.

C.- CZECH REPUBLIC

Instrument of transposition

Like in some other Member States, the Czech legislator has chosen to incorporate the provisions of the Directive into a Regulation (Government Regulation No. 83/2013 of 13 April) which has a more general scope than the Regulation on the prevention from risks associated with the use of sharps. It is a new version of the pre-existing Regulation regarding the protection of workers from risks associated with the exposure to biological agents at work. Therefore, it is a regulation of material implementation whose scope is wider than the one from a specific regulation of transposition of the Directive at hand.

Although there is no objection to this transposition technique, the Czech legislator has been forced to include, in each section of the enacting terms and the Annexes of the Regulation, sentences that underline the implementation of these general provisions regarding the protection from the risks covered by the new Directive. If this transposition technique is not developed with exquisite precision, it is destined to a lack of clarity and precision in its terms.

The use of a Regulation to carry out a transposition seems a good choice to us, in the sense that it is legally binding and effective against third parties. Its provisions are imposed on the recipients of Community obligations effectively enough and thus may be invoked by workers before the national courts and the affected administrations, health care institutions and hospitals.

About the purpose

Article 1.2 of the Regulation includes the prevention of sharps injuries in its purpose. The defining provisions of the purpose are comprehensive enough to cover any situation of risk. To this we must add that Article 2 of the Regulation includes an extensive definition of “sharps”.

Scope and definitions

Most of the definitions provided by the Directive have not been included, which

results in a poor understanding of the national regulation and a lack of precision regarding the interpretation of its provisions.

In order to define its scope, a reference to the "workers of the health care sector" is made without further specification. Therefore, due to its literal sense it does not exclude any typology of worker. However, a specific reference should have been made to the application of the Regulation to all workers, both from the public and private sector.

Risk assessment

We wish to conclude that Article 4 of the Regulation constitutes a correct transposition, although generally referred to the evaluation of risks associated with biological agents.

Elimination, prevention and protection measures

Cross-references to other Articles and Annexes are made in Article 5 of the Regulation, which makes its understanding and implementation extremely difficult.

The incorporation of specific provisions regarding sharps in Article 7 of the Regulation is another example of the chosen transposition technique by extension of the general regulation on risks associated with biological agents. We are missing several specific remarks that would have been necessary regarding the requirements of the new Directive.

Information and awareness-raising

Articles 10 and 11 of the Regulation constitute a correct transposition.

Training

Articles 10 and 11 of the Regulation constitute a correct transposition.

Reporting

There is no specific reference to the reporting obligations of the Directive.

Response and follow-up

Articles 15 and 16 of the Regulation constitute a correct transposition.

Penalty system

There are no references to a general or specific penalty system.

D.- GERMANY

Instrument of transposition

The Directive is transposed into German legislation by means of the Federal Regulation (BioStoffV), which has gradually been incorporating more details and remarks from the EU Directive as the different versions of its drafts were revealed. Since we are before a Regulation, its legally binding nature and general scope should not be questioned. Furthermore, its federal character ensures its implementation throughout the territory of the State. Evidently, this is of utmost importance in Germany.

The German legislator has chosen a transposition technique that consists in widening the scope of the General Regulation on the protection from risks associated with biological agents. In this case, the editor of the regulation has been especially careful and has accurately incorporated all the requirements of Directive 2010/32/EU. For this reason, the chosen transposition technique does not reduce the useful effect of Community provisions.

In Germany, an extensive Pilot Project is being developed to assess the implementation in practice of the requirements of the Directive and to reflect on improvement measures (STOP Nadelstich Project). This Pilot Project is mainly focused on the training of professionals and the selection of material motors and prevention equipment.

About the purpose

Article 1 of the Regulation widens its scope to all workers who “use biomaterials”. This formula is a result of the Regulation’s wide spectrum and the fact that it does not only refer to the risks associated with sharps in the hospital and health care sector, which is covered in any case.

Scope and definitions

The basic definitions of the Directive are included. The definition of “health institution” specifies that this concept covers all workplaces. The terms used suggest

that the Regulation applies both to the public and private sector.

Risk assessment

Articles 4 to 7 of the Regulation constitute a correct transposition. The development made from the implementation of the substitution check-ups technique is very interesting.

Elimination, prevention and protection measures

Articles 8 to 11 of the Regulation constitute a correct and detailed transposition.

Information and awareness-raising

Article 14 constitutes an adequate transposition.

Training

Article 14 constitutes an adequate transposition.

Reporting

Article 17 constitutes an adequate transposition.

Response and follow-up

There is not a specific provision for each of these Directive requirements, except for the one regarding vaccination.

Penalty system

Article 20 of the Regulation develops in detail a penalty system at administrative

level. Although applicable to the whole sector of occupational risks associated with the use of biomaterials, it should be regarded as a complete and detailed system that incorporates provisions relating to each of the obligations of the Directive. Indeed, all the necessary infringements and their penalties are defined.

Article 21 introduces special provisions of criminal nature for cases of intentional or deliberate behaviours.

For all these reasons, it may be considered the most effective transposition carried out by Member States.

E.- NORWAY

Instrument of transposition

Regulation No. 658 of the Ministry of Labour, adopted on 11 June 2013, transposes the Directive. This Regulation amends Regulation No. 1357 of 6 December 2011. On a general basis, it considers the regulation of the use of work equipment and the associated technical requirements.

The regulatory legal nature of the instrument of transposition seems enough to us, since it is legally binding to all (recipients of obligations and beneficiaries of rights) and also bound by the Work Environment Act 17/2005 of 17 June.

In Norway, Directive 2010/32/EU is applied according to its membership of the European Economic Area (EEA) and because said Directive is included among the mandatory Community regulations established in Annex XVIII of the EEA Agreement.

However, as we could verify after having made the transposition control, the Regulation has not incorporated the main obligations of the Framework Agreement or made any reference to an applicable penalty system. Hence, we conclude that this is a very inadequate transposition.

About the purpose

This Regulation of transposition does not incorporate the required reference to the pursued purpose into the pre-existing Regulation. Therefore, this element, which is essential to obtain legal certainty in the compliance of the rest of the obligations, is not transposed.

Scope and definitions

It only adds the definition of “sharps”. However, we must understand that other definitions were already included in the amending Regulation. Nevertheless, the subjective and objective scope is not specified at any time. It does not specify either if the obligations are directed only to public institutions or to private institutions too. We must conclude that we are before an incorrect transposition.

Risk assessment

Section 2 of Article 6.1 of the pre-existing Regulation is amended, which was the regulation of transposition for Directive 2000/54/EC. A last consideration is included regarding the evaluation of risks associated with sharps. It is therefore considered an adequate transposition.

Elimination, prevention and protection measures

The transposition made by amending Article 6.5 seems totally inadequate, since it is just a generic mention to the need for safe protection mechanisms when using sharps. Furthermore, it specifies that these mechanisms will be used “where such equipment is available and appropriate for the purpose”. This sentence leaves the obligations of the Framework Agreement without useful effect. For all this, this is also considered an incorrect and incomplete transposition.

Information, awareness-raising and training

The first paragraph of Article 6.4 is modified, including the information and training considering risks associated with sharps. It is therefore considered an adequate transposition.

Reporting

There are no references in the text so it seems there is a total lack of transposition.

Response and follow-up

There are no references in the text so it seems there is a total lack of transposition.

Penalty system

There are no references in the text so it seems there is a total lack of transposition.

F.- BELGIUM

Instrument of transposition

The Directive is transposed by means of Royal Decree of 17 April 2013, which amends the previous Royal Decree of 4 August 1996 on the protection of risks associated with biological agents at work. The Royal Decree includes all the necessary modifications to carry out the transposition of the new Directive regarding sharps. These Royal Decrees also have the Welfare at Work Act of 4 August 1996 as legal basis, in turn amended by Acts of 7 April 1999 and 10 January 2007. In Belgium, as in many other countries, pre-existing regulations cover most of the requirements.

The lack of participation during the transposition process of social partners of the hospital sector has been criticised.

An explicit reference to the purpose of the Royal Decree is made in its title and in Article 1, which specifies that it is the Directive's instrument of transposition and also mentions the Framework Agreement.

Hence, it constitutes a correct instrument of transposition by regulatory means that ensures, at least formally, the compliance of obligations and the exercise of rights derived thereof.

About the purpose

Article 1 of the aforementioned Royal Decree defines the purpose correctly.

Scope and definitions

It only adds the definition of "sharps". This is because the previous Royal Decree, regarding the general protection against biological agents, already included other definitions that helped to understand and define the scope.

In any case, Article 25/1.1 of the previous Real Decree is added in Article 3 of the Royal Decree, which defines its scope and thus all employers and workers of the hospital and health care sector are covered when using sharps. However, an

explicit reference to its implementation both in the public and private sector should have been made. Taking into account an extensive interpretation of the terms of the Royal Decree, we can consider it an adequate transposition.

Risk assessment

The transposition is correctly detailed by incorporating a new article 25/2.1 which basically includes the requirements of the Framework Agreement.

Elimination, prevention and protection measures

The preventive measures required by the Framework Agreement are correctly referenced by incorporating a new Article 25/2.2.

Information and awareness-raising

Correct transposition, made by the incorporation of a new Article 25/1.2.

Training

Correct transposition, made by the incorporation of a new Article 25/3.

Reporting

Correct transposition, made by the incorporation of a new Article 25/4.

Response and follow-up

Correct transposition, made by the incorporation of a new Article 25/5.

Penalty system

There is a complete lack of transposition.

G.- AUSTRIA

Instrument of transposition

The transposition is made by means of an Order of the Ministry of Labour and is specific to prevention regarding the use of sharps in the hospital and health care sector. It is passed using the Federal Act for Health and Safety at Work (AschG) as legal basis.

Article 7 literally states that it is about the transposition of Directive 2010/32/EU and mentions the Framework Agreement. In this article, referring to Federal Act for Health and Safety, it is noted that implementation decisions contrary to the provisions of the Order cannot be taken.

Despite the fact that this last remark requires the implementation of prevention protocols in accordance with the terms of the Order, it should be noted that this regulation, although legally binding, can be modified at will by the Ministry of Labour. As we have generally explained for all Member States in this Report, this cannot be considered an adequate formula to ensure the compliance of specific obligations derived from the Directive and the Framework Agreement.

Therefore, it is considered an inadequate instrument of transposition.

However, we should note that in some regions of Austria, precautionary measures regarding sharps accidents have been implemented for many years, before the adoption of the Directive. Nevertheless, this situation of implementation is not adequate since it is carried out in a voluntary system that does not provide sufficient legal certainty.

About the purpose

The purpose is well-defined in the title of the Order and in Article 7.

Scope and definitions

Article 1 of the Order defines the subjective and objective scope correctly and with a comprehensive formula, referring to the risk associated with the use of sharps.

It extends to services in transportation, subcontracting, etc. Although it does not specify whether it applies to both the private and public sectors, its extensive diction allows an interpretation in accordance with the provisions of the Framework Agreement.

It only defines the concept of “sharps”. However, the continuous references to the Federal Act for Health and Safety at Work and the General Order on Biological Working Materials (VbA) cover the uncertainty gaps that may arise in its scope. It is noteworthy that one of the basic principles of the Framework Agreement is quoted: “never assume that there is no risk.”

We must conclude that is it an adequate transposition.

Risk assessment

Article 3 of the Order may be considered an adequate transposition.

Elimination, prevention and protection measures

Articles 3.4 and 4 of the Order may be considered an adequate transposition.

Information, awareness-raising and training

Article 5 of the Order, in connection with Articles 12 and 14 of the Occupational Health and Safety Federal Act, covers the requirements of the Framework Agreement.

Reporting

Article 6.1 of the Order, in connection with Article 15 sections 5 and 6 of the Occupational Health and Safety Federal Act, covers the requirements of the Framework Agreement.

Response and follow-up

Article 6.2 and Article 3 of the Order cover the requirements of the Framework Agreement.

Penalty system

There is no mention to a general or specific applicable penalty system. Therefore, there is a complete lack of transposition.

H.- GREAT BRITAIN AND NORTHERN IRELAND

Instrument of transposition

The Directive has been transposed in the UK by Regulation No. 645, devised under the authority of the sectoral Secretary of State and more importantly, approved by Parliament on 21 March 2013, according to the authorisation obtained by the General Act of 1974 for Health and Safety at Work.

The title of the Regulation and its Article 1 state that it is a specific instrument for the prevention of risks associated with sharps in the health care sector. Section 1 of the enclosed Explanatory Note, despite not being a part of the Regulation, states that it is about the transposition of Directive 2010/32/EU and mentions the Framework Agreement.

It is important to note that the last sentence of the first section of this Explanatory Note states that "other requirements of the Directive are implemented by existing regulations." The rest of the Explanatory Note is very clarifying regarding the interpretation that shall be done of each article of the Regulation. However, it does not specify which "other requirements of the Directive" are not part of its provisions for being already included in other previous instruments. Furthermore, it does not include the specific reference to those other previous instruments. This entails an important legal uncertainty.

The legal force is of regulatory nature and therefore it is considered an adequate instrument for transposing, especially since it passes through Parliament. Article 10 of the Regulation includes an important mention concerning the authority of the sectoral Secretary of State to propose amendments or to repeal it. The Explanatory Note specifies that, in any case, such amendments or repeal will always require a new legal "instrument". We interpret that the legal nature of this unnamed "instrument" can only be regulatory, according to the principle of respecting the regulatory hierarchy common to all Member States.

In Northern Ireland the Directive is transposed by means of Regulation 108/2013 of 18 April on Health and Safety (Sharps in Health care), ultimately passed by the Department of Jobs, Enterprise and Innovation on the proposal of the Health and Safety Executive for Northern Ireland. The content of the Regulation, regarding the material obligations of the Directive and the Framework

Agreement, is identical to the one adopted by the UK. As a result, all the conclusions that refer to Regulation of the UK are valid for Northern Ireland.

For all these reasons, it shall be considered a valid instrument of transposition.

About the purpose

As we have previously noted, the title of the Regulation and its Article 1, interpreted by the first point of the Explanatory Note, make its purpose very clear.

Scope and definitions

Definitions are included in Article 2 of the Regulation. Interestingly, a difference between "contractor of the health care sector" and "employer of the health care sector" is established in these definitions. According to Article 3 of the Regulation, it is clear that the latter is included to cover the implementation of the provisions of the Framework Agreement in the field of subcontracting.

Once more, there is no explicit reference to specify if the obligations are imposed on the public and private sector, without distinction. Again, this lack of precision shall be interpreted taking into account the literalness of the provisions, in the most comprehensive sense. In addition, coverage is inadequate because the requirements do not apply to auxiliary personnel.

Article 4.1 limits the implementation of the Regulation to the work performed on the premises of the employer or "under the authority of an employer of the health care sector." Consequently, this statement is enough to conclude that all possibilities provided by the Framework Agreement are contemplated.

Article 4.2 literally limits the implementation of the Regulation to the field of prevention against sharps. However, the Explanatory Note specifies that it limits the implementation to those cases in which the employer "can control" the activity of the worker. We consider that, even if we take into account this interpretation of the Explanatory Note, this limitation of the scope does not infringe the provisions of the Framework Agreement, since an undetermined liability cannot be presumed or required. In other words, an organizational relationship of dependency between the employer and the worker shall always be verified, in order to demand later the

relevant contractual or non-contractual liability for non-compliance.

Hence, we consider the definition of scope as correct.

Risk assessment

No specific transposition measures are considered. Therefore, it is clear that we shall interpret that there is an implicit and generic reference to the Act of 1974 for Health and Safety at Work, at least in this item. Despite this and since no references are made, this transposition technique is clearly inadequate and causes legal uncertainty. This is because it does not consider the specific detail on protocols of risk assessment regarding the use of sharps, as required by the Framework Agreement.

Therefore, we are before an incorrect and incomplete transposition.

Elimination, prevention and protection measures

Article 5 of the Regulation contains provisions that cover the main points of the requirements of the Framework Agreement.

Information and awareness-raising

Article 6, sections 1, 2 and 3 of the Regulation cover the requirements of information and collaboration with workers' representatives, as provided by the Framework Agreement. Requirements are developed in Annex 1.

Training

Article 6.4 and Annex 2 of the Regulation cover the requirements of the Framework Agreement.

Reporting

Article 8 of the Regulation specifies the reporting obligation of workers and Article

7 requires keeping the corresponding record, in accordance with the requirement of the Framework Agreement.

Response and follow-up

In accordance with the requirements of the Framework Agreement, Article 7 of the Regulation imposes the means of response and follow-up.

Penalty system

No reference is made to a general or specific penalty system. Hence, we are before a complete lack of transposition.

I.- SWEDEN

Instrument of transposition

The Directive is transposed by Regulation 7/2012 of 7 December, which amends Regulation 1/2005 on Microbiological Risk in the working environment (infection, toxic effect and hypersensitivity). Both Regulations are passed by the competent authority on Working Environment.

As explained in the first paragraph of the enclosed note, this Regulation in Sweden has a "general" scope and covers prevention in health work and similar environments. Therefore, we shall interpret that we are before a legally binding instrument that goes further than a simple recommendation or guideline regarding its effects, as specified in the Explanatory Note. Furthermore, the Regulation is based on the Work Environment Act 1166/1977 (Section 18).

Accordingly, the Regulation of transposition does not constitute an adequate instrument for transposing Directive 2010/32/EU. This is because it can be modified at will by the competent Authority on Working Environment, following the case of Ministerial Orders in other Member States.

About the purpose

A footnote is included in the Explanatory Memorandum which mentions Directive 2010/32/EU and the Framework Agreement. Thus, it specifies the purpose covering the sector of risks associated with sharps and, in general, of any risk of infection at work (Article 1 of the Regulation).

Scope and definitions

We must take into account that definitions included in the new Article 3 generally refer to biological risks. Specific definitions regarding the sub-sector of risks resulting from the contact with sharps are not introduced.

The enclosed Explanatory Note specifies that the Regulation has a "wide scope". Furthermore, it mentions that it covers the risk associated with the use of sharps. It is also specified that all new provisions will apply to the scope of any risky activity, unless provided otherwise.

Despite these warnings and following the case of most of the examined instruments of transposition in Member States, it does not specify whether it covers any activity both in the public and private sector. As we did regarding the other cases, we chose make an extensive interpretation of the scope.

Therefore, it constitutes a correct transposition.

Risk assessment

It only introduces a new provision (Article 8a) regarding risk assessment in which the existence of such assessment procedures is mentioned. Although according to this generic reference we must interpret that the measures required by the Framework Agreement are included in the pre-existing amending Regulation, we consider that a specific mention should have been made with the necessary references. Thus, we conclude that it is an incorrect technique of transposition.

Elimination, prevention and protection measures

Practically the entire Regulation consists of a detailed specification of measures, many of which define their requirements regarding the sub-sector of prevention of risks associated with the use of sharps: Articles 8a, 11, 18, 19, 22 and 24. Its detail allows us to confirm the coverage of the measures provided by the Framework Agreement.

Information and awareness-raising

The last paragraph of Articles 11 and 14 and Article 15 of the Regulation constitute a correct transposition.

Training

Articles 14 and 15 include the provisions that transpose correctly the requirements of the Framework Agreement.

Reporting

Article 16, concerning the employer, and Article 16a, concerning the worker, constitute a correct transposition.

Response and follow-up

Articles 16b, 16c and 17 constitute a correct transposition.

Penalty system

No reference is made to a penalty system. Therefore, there is a complete lack of transposition.

J.- POLAND

Instrument of transposition

The Directive is transposed by means of a Regulation of the Minister of Health (draft of 6 May 2013) regarding working environments at risk from the use of sharps in the health care sector. It has the Labour Code as legal basis (passed by Act of 26 June 1974, namely Article 23715, paragraph 2). Since it is a Regulation developed by the Labour Code, it is certainly legally binding. However, given that the Ministry is the competent authority for its implementation, it be modified at its own will. For the reasons stated in the first part of this Report, we do not consider it an adequate instrument.

About the purpose

The purpose is correctly quoted in the Regulations' title and Article 1.

Scope and definitions

Article 1.1 of the Regulation describes correctly a maximum scope of subjective and objective coverage. We must interpret that it covers both public and private sector.

Definitions of sharps and worker are included, both concepts to the maximum interpretative extent.

It constitutes a correct transposition.

Risk assessment

Article 3 of the Regulation covers the requirements of the Framework Agreement.

Elimination, prevention and protection measures

Articles 2, 4 and 5 of the Regulation constitute an adequate transposition.

Information and awareness-raising

Article 6 of the Regulation constitutes an adequate transposition.

Training

Article 7 of the Regulation constitutes an adequate transposition.

Reporting

Articles 8 and 10 of the Regulation constitute an adequate transposition.

Response and follow-up

Article 9 of the Regulation constitutes an adequate transposition.

Penalty system

No reference is made to a penalty system. Therefore, there is a complete lack of transposition.

K.- NETHERLANDS

Instrument of transposition

The transposition of the Directive has been partially carried out by the Decree of 22 August 2011 amending the regulation on Working Conditions (Arbo Act and Decree) and its implementing Regulations. Specifically, the only article transposing a specific provision of Directive 2010/32/EU is Article 1H. The explanatory note enclosed with the Decree of partial transposition states that the required new provisions that are missing in the current regulation are introduced by means of this provision, taking into account that the Arbo Decree already "provides a general approach to this type of risks despite it does not list any specific measures".

This explanatory note also includes a comparison table of the national provisions that already incorporate the requirements of the Directive and the Framework Agreement into the national legislation and that cover all their requirements.

The amending Decree is legally binding and of government level. In addition, most of the Directive was already incorporated into in the pre-existing Act and Arbo Decree.

It is therefore considered an adequate instrument of transposition.

About the purpose

The intention to introduce a single provision necessary for the transposition of the Directive is not specified in the recitals of the Decree. Its title, which in turn is generic, does not reflect this fact either. The suitable explanations are only given in the enclosed note of the Secretariat of State for Social Affairs and Employment. Besides, the nature of this note is not regulatory.

Given the above, we conclude that it would have been appropriate to mention the transposition and the fulfilment of the purpose of the Directive due to the existence of a previous regulation and to include that reference in the enacting terms of the Decree.

Hence, this is an incomplete technique of transposition.

Scope and definitions

The scope of the Framework Agreement is explained in the descriptive table of the national legislation that transposes the requirements of the Directive and the Framework Agreement in advance. However, it does not specify whether this scope corresponds to the national regulation (Arbo Act and Decree). In this sense, it shall be considered an inadequate transposition. It does not mention either whether the regulation is applied to both the public and private sector.

However, reference is made to the definitions in said comparison table: Section 1 of the Arbo Act and Article 1.1 of the Arbo Decree.

Risk assessment

An early transposition can be found in Section 5 of the Arbo Act and in Chapter 4, Sections 1, 2, 7, 9 y 10 of Article 2 of the Arbo Decree. It is considered a correct transposition.

Elimination, prevention and protection measures

The only new addition, introduced by the Decree of partial transposition (Article 1H), refers precisely to two specific measures of the Framework Agreement. The rest constitute an early transposition: Sections 3, 5 and 8 of the Arbo Act and Chapter 4, Sections 1, 2 and 9, and Article 8.3 of the Arbo Decree. It is considered a correct transposition.

Information and awareness-raising

An early transposition can be found in Section 5, 8 and 12 of the Arbo Act and in Articles 4.102 and 7.11a of the Arbo Decree. It is considered a correct transposition.

Training

An early transposition can be found in Sections 8 and 11 of the Arbo Act and in

Articles 4.102, 7.11a and 8.3 of the Arbo Decree. It is considered a correct transposition.

Reporting

An early transposition can be found in Sections 9, 11 and 15 of the Arbo Act and in Chapter 4, Articles 1, 2 and 9 of the Arbo Decree. It is considered a correct transposition.

Response and follow-up

An early transposition can be found in Section 9 of the Arbo Act and in Chapter 1, Sections 1, 3 and 4 and Articles 1, 2 and 9 of the Arbo Decree. It is considered a correct transposition.

Penalty system

An early transposition can be found in Sections 32, 33 and 34 of the Arbo Act and in Articles 9.1, 9.9a, 9.9b and 9.9c of the Arbo Decree. It is considered a correct transposition.

Other countries included in the ICF GHK Final Report as of 1 September 2013.

The ICF GHK Final Report covers other countries that have not been subjected to a detailed analysis in this study. Its conclusions are superseded, in the sense that the closing date of said Report is 1 September 2013. We have not been able to verify the documentary sources on which it is based. However, it is worth summarising the fundamental information it provides about some countries.

Bulgaria

The transposition seems to have been done with the collaboration of social partners. There are annual programmes on Working Conditions and Health, and we must take into account the Safety Strategy in the Workplace, both of them national policies. There are also guidelines of behaviour that classify the risk according to the workplace. Trade unions have been closely involved through the respective Committees for risk assessment and prevention. Furthermore, a specific reporting strategy is envisaged.

Croatia

The transposition seems to have been made by means of Ministerial Order No. 84/2013 on Safety Measures for the Prevention of Sharps Injuries. A specific penalty system does not exist.

Cyprus

An Act seems to have been presented to amend the existing regulation and there is a guide applicable to risks from sharps injuries.

Denmark

The Danish Administration considers that no specific measures of transposition are needed. The general regulation covers risk assessment and prevention, and there is a Collective Agreement.

Despite the general nature of the regulation, its implementation has been subjected to an extensive information and training campaign at local level, specifically directed to the risks covered by the Directive.

Estonia

Few measures amending the existing regulation are required to implement the transposition of the Directive. According to the Administration of this country, the transposition was made by guidelines of behaviour.

Finland

A regulation amending the pre-existing regulation was passed after a long negotiating process, with the broad participation of workers' representatives. The concepts of "safe equipment" and "safe working standards" have been discussed at length. Reporting and monitoring obligations, along with the extension of its application to home treatments and social workers have been negotiated in detail.

Hungary

The Decree of transposition was passed by the Ministry of Human Resources (Decree 51/2013 of 16 July). Most of the requirements were already incorporated into pre-existing regulations. Problems arise from the budgetary difficulties for its implementation and also derive from hospital management.

Ireland

The transposition has minimal impact on the pre-existing regulation. Most of the requirements by Act of 2005 relating to the Health and Safety at Work Act and Regulation of 1994, specifically referred to biological agents. The new Regulation of May 2013 specifies the obligations of the employer on risk assessment, preventive measures, training, reporting and safety equipment, in addition to monitoring measures. In practice there are many deficiencies regarding implementation.

Italy

Many obligations are already covered by the pre-existing regulation. Amendments to the Decree were approved in order to extend the scope to students and to extend risk assessment obligations from exposure to blood.

Latvia

Although the transposition requires few formal measures to amend the pre-existing regulation, its implementation is affected by budgetary constraints.

Lithuania

The Directive was transposed by Order of 16 March 2012 (No. A1-157/V-2010/V-501) of the Ministries of Social Security and Labour, Health and Education and Science.

Malta

We only know that the Directive was incorporated under the responsibility of the Ministry of Health.

Romania

It was transposed in May 2013, but budget cuts are limiting its implementation.

Directive 2010/32/EU (Framework Agreement)	Instrument of transposition	Purpose Clause 1	Scope and definitions Clauses 2 and 3	Risk assessment Clause 5	Elimination, prevention and protection measures Clause 6	Information and awareness-raising Clause 7	Training Clause 8	Reporting Clause 9	Response and follow-up Clause 10	Penalty system Art. 2
Spain	X	◊	◊	◊	◊	◊	◊	◊	◊	X
France	X	◊	◊	◊	◊	◊	◊	◊	◊	XX
Czech Republic	◊	◊	X	◊	X	◊	◊	XX	◊	XX
Germany	◊	◊	◊	◊	◊	◊	◊	◊	XX	◊
Norway	X	XX	X	X	X	◊	◊	XX	XX	XX
Belgium	◊	◊	◊	◊	◊	◊	◊	◊	◊	XX
Austria	X	◊	◊	◊	◊	◊	◊	◊	◊	XX
Great Britain and Northern Irland	◊	◊	◊	X	◊	◊	◊	◊	◊	XX
Sweden	X	◊	◊	X	◊	◊	◊	◊	◊	XX
Poland	X	◊	◊	◊	◊	◊	◊	◊	◊	XX
Netherlands	◊	X	X	◊	◊	◊	◊	◊	◊	◊

XX Lack of transposition X Incorrect or incomplete transposition ◊ Correct transposition

CONCLUSIONS OF PART TWO

FIRST

Regarding the eleven countries examined:

a). None of them has fully passed the control of transposition, although Germany and the Netherlands only require certain remarks and supplements which are easily undertaken;

b). Six countries have not used a legal instrument of transposition that grants full guarantee;

c). Only Germany and the Netherlands have incorporated a specific penalty system which is sufficiently respectful of the legal definition principle of offences and penalties; and

d). There is a high level of compliance concerning transposition obligations in terms of material content of the Framework Agreement.

SECOND

None of the examined Member States has chosen to transpose by means of promoting an agreement between the social partners of the sector. We also know that very few Member States have promoted the negotiation of a specific Collective Agreement, a Code of good practice or specific guidelines of behaviour in order to complete the regulation of transposition. Undoubtedly this lack of diligence by national Administrations shall be mitigated by the European Biosafety Network, in close collaboration with the European Agency for Safety and Health and WHO.

THIRD

In order to know the real situation in countries where no information is available and where the transposition could not be examined, the conclusions of this Report shall be contrasted with the technical services of the EU Commission. The services of the EU Commission shall be required to instruct diligently the corresponding

infringement procedures for those cases with a verified complete lack of transposition.

FOURTH

The representative organisation of the profession at European level must provide the services of the EU Commission with a formal complaint against those Member States that have used an inadequate instrument of transposition and against those who have not established a specific penalty system.

FIFTH

Cases of non-compliance by incomplete or incorrect transposition regarding specific obligations of the Framework Agreement must also be reported at European and national level.

SIXTH

An intensive information campaign shall be promoted to professionals of the hospital and health care sector, providing them the rights deriving from Directive 2010/32/EU with clarity, determination and professionalism; supporting, with the help of professional organizations, European and national means of appeal against non-complying Administrations; and promoting simultaneously the widespread filing of complaints and damage claims before national courts and the competent administrative authorities of the occupational risk prevention sector.

SEVENTH

The European Biosafety Network must establish as one of its priorities the promotion and intensification of this control campaign of cases of non-compliance and supporting the exercise of the rights of professionals, establishing a protocol for automatic exchange of information on favourable judgments and administrative decisions. This information and awareness-raising campaign shall be coordinated with EPSU-HOSPEEM and shall consider the ICF GHK Final Report made within

the framework of the Project for the study of the transposition of Directive 2010/32/EU.

EIGHTH

Indeed, there is a satisfactory level regarding the formal obligation of transposition. However, this subject requires that this formal transposition is accompanied by an effective implementation. It is the latter that is far from being properly promoted by the competent authorities, which seem reluctant to detail, develop and explain the obligations by means of Codes of good practice. Undoubtedly, this may be due to budgetary constraints for the implementation of the procedures required and the purchase of the necessary equipment for the effective elimination of accidents. The economic crisis present in some countries may complicate this reality.

GENERAL CONCLUSIONS

The annual number of sharps injuries in the EU is estimated at 1.2 million cases, half of which are not properly reported, without taking into account other accidents associated with the use of sharps.

The protection of health care workers against risks associated with the use of sharp instruments, insofar as objective of the European dimension and essential due to the number and importance of accidents that occur, cannot be jeopardised by complex administrative intricacies regarding the transposition of Directive 2010/32/EU or by intentional concealment or usurpation of rights of professionals that benefit from this recent Community harmonization.