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RAPPORT DU CIB SUR LE CLONAGE HUMAIN ET LA GOUVERNANCE INTERNATIONALE

Le présent rapport a été établi par le Comité international de bioéthique (CIB) sur la base de la réflexion menée en 2008 sur la question du clonage humain et de la gouvernance internationale, notamment les délibérations de son groupe de travail sur la question et le débat tenu lors de la quinzième session du CIB et de la session conjointe du CIB et du Comité intergouvernemental de bioéthique (CIGB) en octobre 2008.

I. CONTEXTE ET MANDAT

1. La question du clonage humain et de ses applications pratiques ainsi que du système international approprié pour sa gouvernance a suscité des réflexions et des discussions approfondies au sein du système des Nations Unies et dans la communauté internationale en général. La réflexion internationale a commencé à l'UNESCO il y a plus de dix ans et conduit à la position consensuelle des États membres sur le clonage à des fins de reproduction énoncée à l'article 11 de la Déclaration universelle de l'UNESCO sur le génome humain et les droits de l'homme (1997). En août 2001, les missions permanentes de la France et de l'Allemagne auprès de l'Organisation des Nations Unies (ONU) ont demandé au Secrétaire général de l'Organisation d'inscrire à l'ordre du jour de la 56^e session de l'Assemblée générale une question supplémentaire intitulée : *Convention internationale contre le clonage des êtres humains à des fins de reproduction*. Une convention internationale serait juridiquement contraignante pour les États membres.

2. À l'issue de près de quatre années de discussion, la Déclaration des Nations Unies sur le clonage des êtres humains a été adoptée (après avoir été mise aux voix) le 8 mars 2005 par l'Assemblée générale des Nations Unies (résolution A/RES/59/280) : 84 États ont voté pour, 34 États ont voté contre et 37 États se sont abstenus. Le texte de la Déclaration permettait des interprétations très différentes, reflétant en partie les divergences entre États membres sur la question. Le fait d'associer le clonage à des fins de reproduction au clonage à d'autres fins constituait le principal point de discordance pour de nombreux États, lesquels se sont abstenus ou ont voté contre la Déclaration.

3. En 2007, l'Institut des hautes études de l'Université des Nations Unies (UNU-IAS) a publié un rapport intitulé *Le clonage des êtres humains à des fins de reproduction est-il inévitable ? Options futures pour la gouvernance des Nations Unies*, qui reprenait les dernières informations techniques sur le clonage, sa dimension éthique et l'état de la gouvernance internationale sur ces questions. Le rapport analysait plus particulièrement la teneur des quatre années de débat de l'Assemblée générale des Nations Unies ayant abouti à l'adoption, après un vote, de la Déclaration des Nations Unies sur le clonage des êtres humains. Les auteurs du rapport estimaient que la gouvernance internationale devait continuer à s'améliorer et faisaient plusieurs propositions en ce sens.

4. Le Directeur général de l'UNESCO ayant exprimé le souhait que l'examen du rapport de l'UNU-IAS soit inscrit à l'ordre du jour de la (des) session(s) du CIB, cette question et celle du clonage humain et de la gouvernance internationale ont été incluses dans le programme de travail du CIB pour 2008-2009.

II. LE RAPPORT DE L'UNU-IAS

5. Le rapport de l'UNU-IAS *Le clonage des êtres humains à des fins de reproduction est-il inévitable ? Options futures pour la gouvernance des Nations Unies* est un document important qui décrit de façon exhaustive l'état actuel de la gouvernance internationale en matière de clonage humain à des fins de reproduction. Bien qu'il soit entendu que ce rapport n'avait pas vocation à présenter un panorama scientifique complet, il a été noté qu'il ne tenait pas compte de plusieurs avancées scientifiques récentes (cellules souches pluripotentes induites, rôle de l'épigénétique dans le développement de l'individu) qui, loin de se résumer à des détails techniques, ajoutent une nouvelle dimension aux questions de bioéthique et de gouvernance.

6. Les options présentées dans le rapport de l'UNU-IAS pour développer des activités futures semblaient limitées car fondées sur des discussions qui ont déjà eu lieu sur ces questions. À cet égard, le rapport décrit surtout ce qu'on ne peut pas faire en raison des divergences actuelles entre les États membres, en particulier quant au statut moral de l'embryon. Il importe de rechercher d'autres approches du problème plutôt que de demeurer dans un cadre où de nombreux arguments reposent sur des distinctions techniques en passe de devenir obsolètes (par exemple, l'utilisation de cellules souches embryonnaires par rapport à d'autres types de cellules souches).

III. ÉTAT ACTUEL DE LA GOUVERNANCE INTERNATIONALE EN MATIÈRE DE CLONAGE HUMAIN

7. À l'échelle internationale, les instruments qui régissent actuellement le clonage humain sont deux déclarations des Nations Unies et une résolution de l'Organisation mondiale de la santé.

8. La Déclaration universelle sur le génome humain et les droits de l'homme, adoptée le 11 novembre 1997 par la Conférence générale de l'UNESCO et faite sienne par l'Assemblée générale des Nations Unies dans la résolution 53/152 du 9 décembre 1998, est le premier instrument international prohibant le clonage d'êtres humains à des fins de reproduction. L'article 11 de la Déclaration énonce ainsi que :

Des pratiques qui sont contraires à la dignité humaine, telles que le clonage à des fins de reproduction d'êtres humains, ne doivent pas être permises. Les États et les organisations internationales compétentes sont invités à coopérer afin d'identifier de telles pratiques et de prendre, au niveau national ou international, les mesures qui s'imposent, conformément aux principes énoncés dans la présente Déclaration.

9. L'Organisation mondiale de la santé (OMS), dans sa résolution WHA 51.10 du 16 mai 1998, déclare que « le clonage pour la reproduction d'êtres humains est inacceptable sur le plan éthique et contraire à la dignité et à l'intégrité de la personne humaine ». Elle « demande instamment aux États membres d'encourager un débat continu et informé de ces questions et de prendre des mesures appropriées, y compris légales et juridiques, pour interdire le clonage à des fins de reproduction d'êtres humains ». Cette résolution confirme une résolution antérieure adoptée par l'Assemblée mondiale de la santé à sa 50^e session en 1997 (WHA 50.37).

10. La Déclaration des Nations Unies sur le clonage des êtres humains du 8 mars 2005 stipule :

- (a) les États membres sont invités à adopter toutes les mesures voulues pour protéger comme il convient la vie humaine dans l'application des sciences de la vie ;
- (b) les États membres sont invités à interdire toutes les formes de clonage humain dans la mesure où elles seraient incompatibles avec la dignité humaine et la protection de la vie humaine.

11. Au niveau régional, le seul instrument qui se réfère explicitement au clonage humain est le Protocole additionnel à la Convention pour la protection des droits de l'homme et de la dignité de l'être humain à l'égard des applications de la biologie et de la médecine, portant interdiction du clonage d'êtres humains, qui a été adopté en 1998 par le Conseil de l'Europe. L'article premier de ce Protocole dispose ce qui suit :

1. Est interdite toute intervention ayant pour but de créer un être humain génétiquement identique à un autre être humain vivant ou mort.
2. Au sens du présent article, l'expression être humain « génétiquement identique » à un autre être humain signifie un être humain ayant en commun avec un autre l'ensemble des gènes nucléaires.

12. À l'échelle nationale, la réglementation applicable à la recherche sur l'embryon humain et au clonage est diverse et reflète les différences culturelles, religieuses, sociales et politiques entre les pays. On trouvera en annexe un examen actualisé des législations nationales.

IV. ACTIVITÉS MENÉES PAR LE CIB EN 2008-2009

13. Pour répondre au souhait du Directeur général, le Bureau du CIB, à sa réunion de janvier 2008, a décidé de créer un groupe de travail sur le clonage humain et la gouvernance internationale, initialement composé de quatre membres : M. Toivo Maimets (Estonie), président, Mme Ephrat Levy-Lahad (Israël), M. Ching-Li Hu (Chine) et M. Gamal Ibrahim Abou Serour (Égypte). Après la quinzième session du CIB (octobre 2008), M. Fernando

Lolas Stepke (Chili) a rejoint le Groupe de travail. La mission assignée à ce Groupe de travail n'est pas de procéder à une nouvelle analyse éthique et scientifique de la question du clonage humain, mais de déterminer s'il existe une évolution scientifique, sociale ou politique qui justifierait une nouvelle initiative internationale.

Première réunion du Groupe de travail du CIB sur le clonage humain et la gouvernance internationale (Paris, 30 juin - 2 juillet 2008)

14. Le Groupe de travail a tenu sa première réunion du 30 juin au 2 juillet 2008 au Siège de l'UNESCO à Paris. Une journée a été consacrée à des auditions publiques de spécialistes de la discipline. Ces auditions, ouvertes à la participation des États membres, ont constitué un point de départ pour les délibérations du Groupe de travail et ont assuré la transparence ainsi que de la clarté quant au mandat et au travail du Comité⁽¹⁾.

15. Les spécialistes suivants sont intervenus : M. Darryl Macer (Professeur adjoint à l'UNU-IAS et l'un des auteurs du rapport de l'UNU-IAS), M. Richard Gardner (Professeur à l'Université d'Oxford), M. Hans Galjaard (Erasmus MC Rotterdam) et Mme Marie-Charlotte Bouësseau (OMS). Les intervenants ont reçu un plan qui incluait les questions suivantes :

1. En août 2001, les missions permanentes de la France et de l'Allemagne ont demandé au Secrétaire général de l'ONU d'inscrire à l'ordre du jour de la 56^e session de l'Assemblée générale une question supplémentaire intitulée « *Convention internationale contre le clonage des êtres humains à des fins de reproduction* ». Après plusieurs années de débat, c'est la Déclaration des Nations Unies sur le clonage des êtres humains, juridiquement non contraignante, qui a été adoptée le 8 mars 2005, en lieu et place d'une convention. Trois ans plus tard, existe-t-il une évolution scientifique, sociale ou politique qui justifierait une nouvelle initiative internationale ?
2. Le rapport de l'UNU-IAS affirme qu'une réglementation internationale est nécessaire dans ce domaine et propose trois possibilités :
 - (a) le CIB réexamine la question du clonage à des fins de reproduction et du clonage à des fins de recherche ;
 - (b) la sixième commission de l'Assemblée générale revoit la question du clonage dans le droit international coutumier ;
 - (c) des informations sont diffusées et des discussions ont lieu à l'échelle internationale sur les questions relatives au clonage afin que tous les pays, y compris les pays en développement et les pays les moins avancés, puissent prendre part au débat et exprimer les préoccupations que leur inspire cette nouvelle technique.

L'une de ces possibilités serait-elle envisageable au regard des différences culturelles, religieuses et sociales existant entre les États membres et de l'intérêt pour eux de développer la recherche médicale en vue de traiter de nombreuses maladies incurables ?
3. Ce même rapport de l'UNU-IAS présente ci-après les différentes possibilités de réglementer le clonage :
 - (a) interdiction totale de toute recherche sur le clonage ;
 - (b) interdiction du clonage à des fins de reproduction ;
 - (c) interdiction du clonage à des fins de reproduction et autorisation du clonage à des fins de recherche ;

1 Les rapports des réunions citées peuvent être consultés en ligne (www.unesco.org/bioethics) ou en s'adressant à la Division de l'éthique des sciences et des technologies de l'UNESCO.

- (d) interdiction du clonage à des fins de reproduction et autorisation du clonage à des fins de recherche pendant 10 ans ;
- (e) institution d'un moratoire sur toutes les recherches portant sur le clonage.

Quelles autres possibilités d'action au sein du système des Nations Unies seraient envisageables et pourraient servir au mieux les intérêts des États membres ?

- 4. Les mots et les définitions que nous utilisons peuvent eux-mêmes commencer à orienter les débats et fixer des limites. Les expressions « clonage reproductifs » et « clonage thérapeutique » introduites dans le débat bioéthique il y a quelques années sont-elles encore adéquates pour décrire les procédés techniques qu'utilisent (ou que pourraient utiliser) les scientifiques aujourd'hui ?

16. À l'issue de la réunion, le Groupe de travail a rédigé un rapport, qui comprenait des informations sur les travaux qu'il avait déjà réalisés, y compris la journée d'auditions publiques, un tour d'horizon des innovations scientifiques, sociales et politiques nécessitant aujourd'hui des initiatives nouvelles en matière de gouvernance internationale sur le clonage humain à des fins de reproduction, ainsi que ses principales suggestions préliminaires (Rapport du Groupe de travail du CIB sur le clonage humain et la gouvernance internationale, document SHS/EST/CIB-15/08/CONF.502/2 du 19 septembre 2008).

Quinzième session du CIB (Paris, 27-29 octobre 2008)

17. Les conclusions préliminaires du Groupe de travail ont été présentées et examinées à la quinzième session (ordinaire) du CIB tenue au Siège de l'UNESCO, à Paris, du 27 au 29 octobre 2008, en présence de plus de 200 participants venus de 89 pays.

18. La séance de travail sur le clonage humain et la gouvernance internationale a été divisée en deux parties : la première partie était consacrée à une deuxième série d'auditions publiques avec des représentants de comités nationaux de bioéthique et d'organisations scientifiques internationales, tandis que la seconde partie était spécifiquement ciblée sur les travaux du Groupe de travail du CIB sur cette question.

19. Les spécialistes intervenus dans ces auditions étaient : M. Dirceu Bartolomeu Greco, membre de la Commission nationale d'éthique de la recherche (CONEP) du Brésil, M. Rajaona Andriamananjara, Président du Comité malgache d'éthique des sciences et des technologies (CMEST), M. Carolus B. Kusmaryanto, membre du Comité national d'éthique de la recherche en santé (KNEPK) de l'Indonésie, et M. Lars Åhrlund-Richter, Professeur d'embryologie moléculaire à l'Institut Karolinska (Suède), représentant de la Société internationale pour la recherche sur les cellules souches. Les auditions ont été organisées suivant le même plan que lors des auditions de juillet (voir ci-dessus).

20. Au cours du débat, certains intervenants ont estimé que le CIB devrait se concentrer sur les aspects du clonage humain et de la gouvernance internationale à propos desquels un consensus semblait pouvoir se dégager, par exemple sur l'interdiction du clonage humain effectué dans le seul but de la reproduction humaine, et réfléchir à la possibilité de renforcer le régime international gouvernant cette pratique.

21. Quant aux développements scientifiques récents, la question centrale abordée par les participants au débat a été celle de savoir si les changements intervenus étaient suffisants pour justifier de nouvelles initiatives internationales concernant la gouvernance : certains intervenants ont soutenu qu'il ne s'était pas produit de changements notables, mais d'autres ont fait observer que les nouveaux progrès dans la production de cellules iPS et de cellules hybrides figurent parmi les facteurs émergents qui soulèvent la question de la nécessité de renforcer les mécanismes existants de gouvernance en matière de clonage humain.

22. Plusieurs participants ont fait écho au Groupe de travail du CIB en soulignant combien les termes et les définitions employés dans ce domaine ont eux-mêmes soulevé des débats et créé des clivages : les expressions « clonage reproductif » et « clonage thérapeutique » introduites dans les débats sur la bioéthique il y a plusieurs années ne décrivent pas adéquatement les procédures techniques utilisées (ou qui pourraient l'être) aujourd'hui. Il a donc été demandé de réfléchir sur cette question.

Session conjointe du CIB et du CIGB (Paris, 30-31 octobre 2008)

23. La session conjointe du CIB et du CIGB, convoquée par le Directeur général au Siège de l'UNESCO à Paris les 30 et 31 octobre 2008, a été l'occasion pour le CIB d'entendre les observations des membres du CIGB et a permis un libre échange de vues entre les membres des deux comités.

24. Le thème dominant de nombreuses interventions a été la nécessité de trouver un juste équilibre entre le fait d'interdire les pratiques de clonage humain à des fins strictement de reproduction - question sur laquelle un consensus international semble se dégager - et le fait d'autoriser les chercheurs travaillant sur les cellules souches à poursuivre leurs efforts dans un cadre éthiquement réglementé en vue de trouver des traitements à des maladies aujourd'hui incurables et d'accéder à une meilleure compréhension de la physiologie humaine.

25. À cet égard, si plusieurs participants ont relevé ce qui semblait être une unité de vues contre le clonage humain à des fins de reproduction, faisant naître l'espoir d'un engagement international en faveur d'un régime juridiquement contraignant sur la question, il a néanmoins été jugé extrêmement important de rappeler le débat politique qui a eu lieu à l'Assemblée générale des Nations Unies en 2005 lorsque, en raison des divergences fondamentales entre les positions des États membres, la Déclaration, non contraignante, des Nations Unies sur le clonage humain avait été adoptée après avoir été mise aux voix. La plupart des intervenants ont fait remarquer que, vu que les positions des pays restaient relativement inchangées depuis 2005, il serait contre-productif que l'UNESCO rouvre le débat sans garantie raisonnable de parvenir à une position consensuelle.

26. Cela étant, le fait qu'il n'existe guère, voire pas, de réglementation spécifique sur le clonage humain dans les pays en développement et les pays les moins avancés a été rappelé avec insistance. Un tel fait est apparu clairement lors de la quatorzième session du CIB tenue à Nairobi (mai 2007), lorsque des spécialistes de la région africaine ont témoigné de l'absence de réglementation ou de législation nationale sur les biotechnologies et les questions connexes en Afrique subsaharienne, surtout en ce qui concerne le clonage humain à des fins de reproduction. Dans les pays en développement et les pays les moins avancés, cette absence de réglementation nationale entraîne une vulnérabilité des individus face à des recherches scientifiques et technologiques extérieures et dictées par le profit. Dans de telles circonstances, un instrument international juridiquement plus contraignant servirait la protection des intérêts de ces nations et de leur population. Pour de nombreux participants, il ne fallait donc pas s'abstenir de débattre ouvertement des moyens de réglementer effectivement le clonage humain au niveau international.

V. ÉVOLUTION SCIENTIFIQUE, JURIDIQUE ET SOCIALE : ANALYSE PRÉLIMINAIRE

27. La réflexion et la discussion au sein du CIB ont principalement porté sur la question préliminaire de savoir si des changements suffisamment importants dans les domaines scientifique, juridique ou social justifiaient un réexamen des mécanismes de gouvernance internationale relatifs au clonage humain. Dans le cadre de cette réflexion, le CIB s'est également penché sur la question de la terminologie employée et sur la distinction entre clonage thérapeutique et clonage reproductif.

28. D'un point de vue scientifique, il semble qu'un certain nombre de nouvelles avancées scientifiques puissent avoir un impact sur l'évolution de la gouvernance internationale en matière de clonage. D'une part, les travaux réalisés depuis 2006 sur les cellules souches pluripotentes induites (iPS) et leurs possibles usages ont créé de nouvelles possibilités techniques dans la manipulation d'embryons humains à des fins de reproduction, générant de ce fait de nouvelles problématiques. Depuis qu'il a été démontré que des cellules germinales fonctionnelles pouvaient être créées à partir de cellules souches embryonnaires, la possibilité de produire des cellules germinales à partir de cellules somatiques (via des cellules iPS) a été envisagée, rendant un peu plus floues les frontières entre les différentes étapes du développement humain et de la reproduction. En outre, le financement de la recherche sur l'embryon humain a considérablement augmenté ces dernières années, tandis que les intérêts commerciaux privés de multinationales se font de plus en plus présents dans ce domaine. Ceci s'accompagne d'un trafic international (légal et illégal) d'embryons, d'ovules et de cellules souches.

29. D'autre part, il est clair pour les scientifiques que le « clonage », au sens de la création d'êtres humains identiques, est impossible en raison de la diversité des situations en matière de développement et d'environnement, des modifications épigénétiques de l'ADN concerné, etc. D'un point de vue scientifique, il est en outre évident qu'en l'état actuel de la technique, le clonage à des fins de reproduction s'accompagne de risques sérieux pour la santé des femmes comme des fœtus. Le terme « clone » prête donc à confusion sur les plans scientifique et étymologique, dans la mesure où il ne tient pas compte des différences qui existeraient entre une personne et son « clone génétiquement identique ». Il convient à cet égard de souligner l'importance des facteurs épigénétiques. On a toutefois reconnu qu'il ne fallait pas abandonner le terme de « clonage », étant donné qu'il était déjà employé dans un certain nombre de lois nationales et de directives internationales actuellement en vigueur.

30. De la même façon, les expressions « clonage reproductif » et « clonage thérapeutique » introduites dans les débats sur la bioéthique il y a plusieurs années ne décrivent pas adéquatement les procédures techniques utilisées (ou qui pourraient l'être) aujourd'hui. Si le terme de « clonage reproductif » indique clairement l'objectif ultime du processus, celui de « clonage thérapeutique » n'est pas sans ambiguïté quant au but poursuivi, étant donné qu'aucun processus de clonage n'a débouché sur des applications thérapeutiques à ce jour. L'ambiguïté est principalement due aux différents statuts attribués à l'embryon humain selon les cultures et les sociétés. Si la controverse continue de porter sur le statut moral de l'embryon, alors il n'est guère possible de parvenir à un consensus. Cependant, ainsi qu'il a été détaillé précédemment, le clonage à des fins de reproduction pourrait devenir possible sans embryons. Il est donc à l'évidence nécessaire d'appréhender la gouvernance internationale sur le clonage en termes d'éthique, ce qui permettrait aux différents pays de s'accorder, par exemple sur l'interdiction du clonage à des fins de reproduction.

31. D'un point de vue juridique, plusieurs États membres ayant récemment mis à jour leur réglementation nationale en matière de gouvernance sur le clonage humain et la recherche embryonnaire en général, leurs responsables politiques sont plus conscients et mieux informés de ces questions. L'examen des législations nationales montre qu'une convergence de vues apparaît quant au refus d'adopter des lois ou des directives autorisant le clonage à des fins de reproduction. Mais pour ce qui est d'autres techniques de développement de la recherche sur l'embryon humain, les réponses nationales en matière de réglementation sont beaucoup plus diverses. Des divisions marquées subsistent quant à la légitimité du clonage humain pratiqué dans le cadre des programmes de recherche même si l'objectif est d'approfondir la connaissance en biologie ou de contribuer à la mise au point de traitements efficaces pour des maladies aujourd'hui incurables.

32. Il convient d'autre part de souligner que si certains pays ont adopté des réglementations spécifiques sur le clonage humain, beaucoup d'autres, en particulier parmi les pays en développement, n'ont toujours pas de réglementation en la matière, ce qui entraîne une vulnérabilité des individus face à des recherches scientifiques et

technologiques extérieures et dictées par le profit. Dans de telles circonstances, l'existence d'un instrument international juridiquement contraignant plus solide en matière de clonage humain reproductif servirait la protection des intérêts de ces nations et de leur population.

33. Enfin, au cours des quelques années écoulées depuis l'adoption de la Déclaration des Nations Unies sur le clonage des êtres humains, le grand public a pris conscience de ces questions et y est de plus en plus sensible. En revanche, l'information les concernant et la façon dont elle est diffusée pourraient être améliorées. L'une des options de gouvernance internationale mentionnée dans le rapport de l'ONU-IAS (p. 26) est « la diffusion d'informations, la discussion et le débat à l'échelle internationale » sur les questions relatives au clonage afin que tous les pays, y compris les pays en développement et les pays les moins avancés, puissent prendre part au débat et faire connaître leurs préoccupations vis-à-vis de cette nouvelle technique. Il conviendrait de mettre en place activement des mesures en ce sens, parallèlement à d'autres actions normatives possibles.

VI. RÉSUMÉ ET CONCLUSIONS

34. La complexité des questions éthiques soulevées par le clonage humain est aussi profonde que la variété des perspectives religieuses et culturelles existant sur cette question à travers le monde. La diversité des opinions à cet égard n'est guère surprenante si l'on considère que le clonage d'un être humain, que ce soit à des fins de reproduction ou de recherche, élude la question fondamentale de la dignité de la vie, du commencement de la vie et du statut de l'embryon.

35. Répondant au souhait du Directeur général, le Comité international de bioéthique (CIB) a essayé de déterminer si des changements suffisamment importants dans les domaines scientifique, juridique ou social justifiaient un réexamen des mécanismes de gouvernance internationale relatifs au clonage humain et la proposition de nouvelles initiatives.

36. Compte tenu de la réflexion et des débats qui ont eu lieu en 2008-2009, le CIB a établi ce qui suit :

- Des changements se sont produits au cours des trois dernières années qui sont susceptibles d'avoir un impact sur l'évolution de la gouvernance internationale en matière de clonage : nouvelles avancées scientifiques, comme la recherche sur les cellules souches pluripotentes induites (iPS) et ses applications ; trafic international (légal et illégal) accru d'embryons, d'ovules et de cellules souches ; sensibilisation et information accrues du public parallèlement au développement des règles nationales de gouvernance en matière de clonage humain et de la recherche embryonnaire en général (voir section V ci-dessus). Les avancées scientifiques dans des domaines comme les cellules iPS, en particulier, ouvrent de nouvelles possibilités pour la recherche et, à moyen terme, pour des applications thérapeutiques, mais elles posent aussi de nouveaux défis et problèmes éthiques qui exigent une réflexion et une discussion plus poussées.
- La terminologie employée dans les débats sur la bioéthique est trompeuse et ne décrit pas correctement les procédures techniques utilisées (ou qui pourraient l'être) aujourd'hui. Une analyse approfondie visant à redéfinir cette terminologie compte tenu des nouvelles avancées dans la recherche sur l'embryon humain serait extrêmement utile.
- Les règles nationales de gouvernance en matière de clonage humain et de recherche sur l'embryon en général qui ont été adoptées à ce jour confirment la convergence de vues quant au refus d'adopter des lois ou des directives autorisant le clonage à des fins de reproduction, mais font encore apparaître des divergences au sujet de la légitimité du clonage humain effectué dans le cadre de programmes de recherche.

- De nombreux pays, en particulier parmi les pays en développement, n'ont toujours pas de réglementations spécifiques sur le clonage humain. Une réglementation claire et effective du clonage humain reproductif à l'échelle internationale servirait grandement la protection des intérêts de ces nations et de leur population.
- La technologie requise pour donner naissance à un être humain par le clonage n'existe pas encore, mais elle pourrait être mise au point dans un avenir proche et les instruments internationaux non contraignants actuellement en vigueur concernant le clonage humain (c'est-à-dire la Déclaration universelle sur le génome humain et les droits de l'homme de l'UNESCO de 1997 et la Déclaration des Nations Unies sur le clonage des êtres humains de 2005) ne suffisent pas à empêcher le clonage humain à des fins de reproduction.
- La diffusion d'informations, la discussion et le débat à l'échelle internationale sur les questions relatives au clonage demeurent essentiels pour sensibiliser et informer le public, afin que tous les pays, y compris les pays en développement et les pays les moins avancés, puissent prendre part au débat et faire connaître leurs préoccupations vis-à-vis de cette nouvelle technique. De telles activités sont très importantes et devraient être activement mises en œuvre, parallèlement à d'autres actions normatives possibles.

37. Compte tenu de ces observations, le CIB est d'avis que, bien qu'il soit sans doute prématuré pour la communauté internationale de s'engager dès à présent dans l'élaboration d'un instrument normatif contraignant visant à harmoniser à la fois les pratiques et les principes dans ce domaine, les questions entourant la gouvernance internationale en matière de clonage humain ne peuvent être ignorées et il est urgent d'engager à ce sujet un dialogue à l'échelle internationale. L'UNESCO, forte de son mandat éthique qui n'a toujours pas d'équivalent dans le système des Nations Unies et de ses réalisations normatives dans le domaine de la bioéthique (Déclaration universelle sur le génome humain et les droits de l'homme de 1997, Déclaration internationale sur les données génétiques humaines de 2003 et Déclaration universelle sur la bioéthique et les droits de l'homme de 2005), est particulièrement bien placée pour poursuivre cette réflexion d'une manière à concilier la multiplicité des points de vue sur la question et pour étudier les aspects éthiques des nouvelles avancées scientifiques et leur impact sur le cadre normatif international actuel.

38. À cet effet, l'UNESCO devrait associer dans la mesure du possible d'autres institutions des Nations Unies, en particulier l'Organisation mondiale de la santé (OMS). Elle devrait également consulter les organisations scientifiques nationales, les entités de bioéthique, la société civile et tous les autres groupes susceptibles d'être concernés.

39. Dans ce contexte, le CIB est prêt à continuer de jouer son rôle dans le système international de bioéthique et dans le débat sur le clonage humain et sa réglementation internationale, avec le Comité intergouvernemental de bioéthique (CIGB), ainsi qu'à faire part au Directeur général et aux États membres des résultats de ses travaux, et, le cas échéant, de ses suggestions et des orientations possibles en vue d'un engagement plus actif dans ce domaine au cours des prochaines années.

40. Enfin, le CIB estime que l'UNESCO pourrait mettre au point des stratégies et des instruments spécifiques pour promouvoir le débat international sur cette question et encourager et aider plus activement les organisations/universités nationales de recherche et les comités nationaux de bioéthique à diffuser des informations et discuter des questions de clonage.

Study on National Legislation concerning Human Cloning

This document presents an overview of existing legal framework concerning human cloning. It does not pretend to be exhaustive and will be periodically revised².

Table 1 is limited to national legislation on human cloning and does not include:

- 1) national *guidelines*, even if these guidelines are, in state practice, applied in the same manner as laws.;
- 2) patents laws that prohibit granting of a patent for processes intended to lead to human cloning;
- 3) public national laws that guarantee the fundamental human rights such as human dignity or the human rights in biomedical research. It should be noted that in view of official positions from governments and/or national bioethics bodies in these countries, human cloning directly violates these fundamental rights and is therefore banned;
- 4) provisions which could be interpreted as banning human cloning if such interpretation has not been legally implemented by a convention or a court decision.

Not being listed in this table does not mean that a country has no human cloning policy, or that it does not apply it. Indeed, many countries have opted for *guidelines* in order to regulate human cloning activities or have officially expressed their position through governmental declarations or by official recommendation of national bioethics bodies.

Furthermore, some countries, having ratified conventions related to the ban of human reproductive cloning, have applied its provisions without adopting specific domestic legislation on it. These countries can be found in Table 2 related to international treaties and conventions.

A note on main sources

Because many national sources are unavailable on the web or not translated, this table is using many reliable secondary sources like Digest of Legislation of WHO or Official reports. When the legal text is available and translatable, the provision is cited directly; when only a reliable secondary source is mentioned, a summary replaces the original wording.

². Any information on relevant law and regulations that could assist in updating this document should be addressed to the division of Ethics of Science and Technology (fax +33 (0) 45 68 55 15; e-mail: s.colombo@unesco.org).

Table I – National legislation

STATES	DOMESTIC LAWS			
	REPRODUCTIVE CLONING		RESEARCH/THERAPEUTIC CLONING	
	Reference	Main Provisions	Reference	Main Provisions
Argentina	<p>Presidential Decree n°200/97 on the Prohibition on Human Cloning Research of 7 March 1997</p> <p>REGIONAL LAWS</p> <p><u>Province of Mendoza</u> Mendoza Law n°6581 on the prohibition of human cloning experiments of 24 March 1998</p> <p><u>Province of Neuquén</u> Law n°2258 on the creation of a permanent provincial commission on fecundation and genetic research of 15 October 1998</p> <p><u>Province of Jujuy</u> Law n°5133 establishing a Program for responsible maternity and paternity of 3 June 1999</p> <p><u>Province of Cordoba</u> Law n° 6222 on practices and activities in relation with human health of 17 November 1978 as amended by Law n° 9072 of 13 January 2003</p>	<p><u>Article 1:</u> Cloning experiments in relation with human beings are prohibited.</p> <p><u>Section 1:</u> Cloning experiments in relation with human beings are prohibited on the whole territory of Mendoza.</p> <p><u>Article 5:</u> Cloning practices, creation of hybrids, trade of human gametes and of cryoconserved embryos remain prohibited, with severe sanctions at stake.</p> <p><u>Article 3:</u> Every health institution depending upon the Welfare Ministry will offer the following services and cares: f) Providing information and access to treatment of infertility and sterility except for cloning and other methods in contradiction with ethics [...].</p> <p><u>Article 7:</u> It is prohibited to: [...] s) Create human reproduction by the technique of cloning, in the understanding that such a process leads to the creation of a human being derived from a unique individual without the characteristics of sexual reproduction”.</p>	<p><i>IDEM</i></p> <p><i>IDEM</i></p> <p><i>IDEM</i></p> <p><u>Province of the autonomous city of Buenos Aires</u> Law n°712/2001 safeguarding human gene pool</p>	<p><u>Article 1:</u> Cloning experiments in relation with human beings are prohibited.</p> <p><u>Section 1:</u> Cloning experiments in relation with human beings are prohibited on the whole territory of Mendoza.</p> <p><u>Article 5:</u> Cloning practices, creation of hybrids, trade of human gametes and of cryoconserved embryos remain prohibited, with severe sanctions at stake.</p> <p><u>Section 14:</u> The City adopts as program, for the regulation and the interpretation of good practice in research on human genome and its applications, the Universal Declaration on Human Genome and the Human rights of UNESCO of 11 November 1997 (Annex I) (Ref. Article 11).</p>

<p>Australia*</p>	<p>The Prohibition of Human Cloning for Reproduction Act of 19 December 2002 as amended by Act n°172 of 12 December 2006</p> <p><i>Notice of variation</i> signed between the Commonwealth, the States and the Australian Capital Territory of 13 April 2007.</p>	<p><u>Section 9:</u> A person commits an offence if the person intentionally places a human embryo clone in the body of a human or the body of an animal. Maximum penalty: Imprisonment for 15 years.</p> <p><u>Section 20 (3):</u> A person commits an offence if the person intentionally places an embryo in the body of a woman knowing that, or reckless as to whether, the embryo is a prohibited embryo. Maximum penalty: Imprisonment for 15 years.</p> <p><u>Comment:</u> Prohibited embryos are notably embryos “<i>created by a process other than the fertilization of a human egg by human sperm</i>”. (Section 20 (4) of the Act)</p> <p>The States, ACT and the Commonwealth signed an Intergovernmental Agreement for the implementation of the legislation adopted in 2006 consisting in the ban of reproductive cloning.</p>	<p><i>IDEM</i></p> <p><i>IDEM</i></p>	<p><u>Section 22:</u> A person commits an offence if: (a) the person intentionally creates a human embryo by a process other than the fertilization of a human egg by a human sperm, or develops a human embryo so created; and (b) the creation or development of the human embryo by the person is not authorised by a licence. (1)</p> <p>This agreement consists in implementing a national consistent legislative scheme on human embryo research as well.</p>
<p>Austria**</p>	<p>Federal Law on Reproductive medicine of 1992 as modified in 2001 and 2004 (n°98/2001 and n°163/2004)</p>	<p>Article 9 of this law prohibits implicitly human reproductive cloning as it prohibits the use of human embryos (fertilized eggs) for another purpose than the medically assisted procreation which is, itself, submitted to strict restrictions. A violation is subject to administrative or criminal prosecution.</p>	<p><i>IDEM</i></p>	<p>Research on embryonic cells is prohibited for the same reason.</p>
<p>Belgium*</p>	<p>In Vitro Embryos Research Act dated of 11 May 2003</p>	<p><u>Article 6:</u> Human reproductive cloning is forbidden.</p> <p><u>Article 13:</u> Any person who commits a forbidden intervention prohibited by articles 3 (5), 4, 5 or 6 of this law is liable to a 1 to 5 years imprisonment penalty and/or a 1000 to 10000 Euros fine.</p> <p><u>Article 14:</u> Without prejudice to article 13, any condemnation for the facts forbidden by article 6 is liable to a 5 years ban of exerting any medical or research activity.</p>	<p><i>IDEM</i></p>	<p><u>Article 3:</u> Research on in vitro embryos is allowed if all requirements of this law are respected and notably if: 1° It has a therapeutic objective or aims at improving knowledge in the fields of fertility, sterility, transplant of organs or tissues, prevention or treatment of diseases. [...] 5° It is carried during the embryo 14 first days of development, freezing period not included. 6° There is no alternative research method providing a corresponding effectiveness.</p> <p><u>Article 4:</u> §1. The creation of embryos for research purposes is forbidden excepted if the aim of the research cannot be reached by research on excess embryos and only if all requirements of this law are respected.</p>

* Countries that have a legislative ban on reproductive cloning and the corresponding penal provisions.

** Countries with a ban on reproductive human cloning, but without penal provisions.

<p>Brazil*</p>	<p>Law n°11105 on Biosecurity of 24 March 2005</p>	<p><u>Art. 6:</u> The following activities, inter alia, are prohibited: [...] human cloning.</p> <p><u>Art. 26:</u> Performing human cloning is punished by a 2 to 5 years imprisonment penalty and a fine.</p>	<p><i>IDEM</i></p>	<p><u>Art. 5:</u> Embryonic stem cells obtained from human embryos produced by in vitro fertilization and not used in the respective procedure may be used for research and therapeutic purposes, provided that the embryos are non-viable or have been frozen for three years or more prior to the publication of this Law.</p> <p><u>Art. 6:</u> The following activities, inter alia, are prohibited: genetic engineering involving human germline cells, human zygotes, or human embryos; and human cloning.</p> <p>Comment: The Brazilian Supreme Court upheld this legislation allowing stemcell research by a decision of 29 May 2008. However, research cloning is excluded as the human cloning prohibition covers both reproductive and therapeutic hypothesis (Art. 3).</p>
<p>Bulgaria</p>	<p>Order n°28 of 20 June 2007 on assisted reproduction</p>	<p><u>Art. 1. (1)</u> This regulation: 1. approves medical standards for assisted reproduction under Annex № 1;</p> <p><u>Annex № 1 to Art. 1, para. 1, item 1</u> Medical standards regarding "assisted reproduction" [...] Section IV Medical-biological activities and laboratory methods used for assisted reproduction: [...] 3. When carrying out assisted reproduction it is not permitted: [...] 3.12. to perform reproductive cloning; [...]</p>	<p>Health Act 2004 n°70 as amended in 2008</p>	<p><u>Art.134.</u> [...] 2) [...] Ovum, sperm and fertilized ovum that are not used to produce offspring, can be provided to scientific, educational and medical institutions in the State and abroad for medical, scientific and educational purposes after obtaining the written and informed consent of the donor, and in the case of fertilized eggs, of both donors, through a procedure established by order of the Minister of Health.</p> <p><u>Art.135.</u> [...] (2) The use of assisted reproduction techniques for the transfer of the genetic information of a single individual to his descendants is prohibited. (3) The reproductive cloning of human beings is prohibited, including if its purpose is the donation of organs, tissues and cells.</p> <p>Comment: Research on embryos and gametes is allowed to a certain extent however research cloning is prohibited.</p>
<p>Canada*</p>	<p>The Assisted Human Reproduction Act, 29 March 2004</p>	<p><u>Section 3:</u> "human clone" means an embryo that, as a result of the manipulation of human reproductive material or an <i>in vitro</i> embryo, contains a diploid set of chromosomes obtained from a single — living or deceased — human being, foetus or embryo.</p>	<p><i>IDEM</i></p>	<p><u>Section 5 (1) (a):</u> No person shall knowingly create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device;</p>

		<p><u>Section 5 (1) (a):</u> No person shall knowingly create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device;</p> <p><u>Section 60:</u> A person who contravenes any of sections 5 to 9 is guilty of an offence and :</p> <p>(a) is liable, on conviction on indictment, to a fine not exceeding \$500,000 or to imprisonment for a term not exceeding ten years, or to both; or</p> <p>(b) is liable, on summary conviction, to a fine not exceeding \$250,000 or to imprisonment for a term not exceeding four years, or to both.</p>		<p><u>Section 5 (1) (b):</u> No person shall knowingly create an <i>in vitro</i> embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures.</p> <p><u>Section 60:</u> A person who contravenes any of sections 5 to 9 is guilty of an offence and (a) is liable, on conviction on indictment, to a fine not exceeding \$500,000 or to imprisonment for a term not exceeding ten years, or to both; or (b) is liable, on summary conviction, to a fine not exceeding \$250,000 or to imprisonment for a term not exceeding four years, or to both.</p> <p>Comment: It appears that the creation of in vitro embryos is allowed for very limited research purposes (Section 5 (1) (b)). Nevertheless, research cloning remains prohibited as section 5 (1) (a) prevents the creation of a clone for any reason.</p>
Chile*	Law n°20120 of 7 September 2006 concerning scientific research on the human being, the human genome and the prohibition of cloning	<p><u>Article 5:</u> This provision prohibits the cloning of human beings whatever the purpose or the method used.</p> <p><u>Penal:</u> According to article 17 of this law, a person guilty of cloning a human being would be liable to imprisonment and to an interdiction of exercising his profession.</p>	IDEM	<p><u>Article 6:</u> This provision authorizes the culture of tissues and organs but only for diagnostic purposes or scientific research and prohibits the destruction of human embryos to obtain stem cells to give rise to such tissues and organs. Hence, research cloning is prohibited.</p> <p><u>Penal:</u> The same penalties as for reproductive cloning have been prescribed.</p>
China**	Ethical Guiding principles for research on Human Embryonic Stem cells (2003-460)	<p><u>Article 4:</u> Any research aiming at human reproductive cloning shall be prohibited in the People's Republic of China.</p>	IDEM	<p><u>Article 5:</u> Human embryonic stem cells used for research purpose can only be derived from the following means with voluntary agreement: [...] Embryos obtained by somatic cell nuclear transfer technology or parthenogenetic split embryos;</p> <p>Comment: Thus, research cloning is allowed.</p>

	<p>Hong Kong special administrative region Human Reproductive Technology Ordinance n°47 of 2000 as amended by law n°106 of 2002 and law n° 130 of 2007.</p>	<p>Section 15: 1) No person shall: (e) replace the nucleus of a cell of an embryo with a nucleus taken from any other cell; or (f) clone any embryo.</p> <p>Comment: Penal provisions are to be issued by the Ministry of Health and the Council on Human Reproductive Technology.</p>	<p><i>IDEM</i></p>	<p>Section 15: 1) No one shall: (a) for the purposes of embryo research (i) bring about the creation of an embryo; [...] (f) clone any embryo</p> <p>Section 21: A person may make an application to the Council to be granted a licence to carry on a relevant activity in premises specified in the application.</p> <p>Section 2: "relevant activity" means an activity which consists of or involves- [...] (b) the conducting of embryo research;</p> <p>Comment: Though research on embryos is allowed in a certain respect, research cloning is excluded from this scope.</p>
<p>Colombia*</p>	<p>Law n°599 of 24 July 2000 establishing a new criminal code which introduces a Chapter 8 on genetic manipulation</p>	<p>Article 133 of the Colombian criminal code: <i>Human being duplication</i> -Those who would be creating identical human beings by cloning or by any other process would be liable to a 2 to 6 years imprisonment penalty.</p>	<p><i>IDEM</i></p>	<p>Article 132 and 134 respectively only prohibit the manipulation of human genes that could alter the genotype and the fertilization of human eggs if those experiments are carried out for a different purpose than scientific research, treatments or diagnostics. In this perspective, research cloning is allowed in Colombia.</p>
<p>Costa Rica**</p>	<p>Case law n°2000-02306 by the Supreme Court invalidating Decree n°24029-S on "In Vitro Fertilization and Human embryos transfer" of 3 February 1995</p>	<p>Human reproductive cloning is not prohibited by law but is commonly condemned like any manipulation of embryos. The Supreme Court decision can be clearly interpreted in this sense as it is strongly pointed out that any intervention endangering embryos which is not in its own interests shall be prohibited.</p>	<p>Case law N°2000-02306 by the Supreme Court invalidating Decree n°24029-S on "In Vitro Fertilization and Human embryos transfer" of 3 February 1995</p>	<p>By this decision, Costa Rica's Supreme Court declared in vitro fertilization to be unconstitutional, considering it an offence to the human right to life which understands embryos as human beings from the day of their conception. This decree was censured for both legal and technical reasons as this is not a matter that can be ruled by the executive body and because of the technical aspects which endanger embryo life. It appears that all embryo manipulation shall be prohibited.</p>
<p>Czech Republic*</p>	<p>Act on Human Embryonic Stem Cell Research Law n° 227/2006 of 26 April 2006</p>	<p>Section 3: (3) Such manipulations (stem cells research) with human embryonic stem cells must be prevented within the research which could lead to creation of a new human individual (reproductive cloning).</p> <p>Section 20: Penal code amendments (1) Who: [...] f) Manipulates the human embryonic stem cells during their research in a way leading to creation of a new human individual (reproductive cloning), shall be punished by imprisonment up to three years or ban on activity. Comment:</p>	<p><i>IDEM</i></p>	<p>Section 3: (1) Research on human embryonic stem cells may be conducted only on the basis of a permission issued by the Ministry of Education, Youth and Sport [...]</p> <p>Section 20 9 b: Penal code amendments (1) Who a) performs interventions leading to creation of a human embryo for purposes other than implantation into a woman's body, [...] shall be punished by imprisonment up to three years or ban on activity.</p>

<p>El Salvador**</p>	<p>Politic Constitution of El Salvador of 15 December 1983 as amended in 2003</p> <p>Penal Code of El Salvador entered in force on 20 April 1998</p>	<p><u>Article1:</u> El Salvador recognizes human persons as the origin and the end of States activities [...]. It recognizes as Human persons all Human beings from the day of their conception [...]</p> <p>Comment: The recognition of human beings as human person from their conception results from a constitutional amendment operated by law nº 541 of 3 February1999.</p> <p><u>Article 140:</u> [...] The same penalty (3 to 6 years of prison) will be applied to a person who experiment or manipulate cloning with human cells in view of reproducing human beings.</p>	<p><i>IDEM</i></p> <p><i>IDEM</i></p>	<p><u>Article 137:</u> Those who guiltily will provoke an abortion will be liable to 6 months to 2 years imprisonment penalty.</p> <p>Comment: Human beings are considered constitutionally as human persons from their conception. Research cloning and therapeutic cloning, as provoking the death of the embryo, could be also considered as a voluntary abortion.</p>
<p>Estonia*</p>	<p>Penal code §130 (adopted on 6 June 2001)</p>	<p><u>§ 130 - Prohibited acts with embryo:</u> Human cloning or creating a human hybrid or human chimera is punishable by a pecuniary punishment or up to 3 years' imprisonment.</p>	<p>Penal code §131 (adopted on 6 June 2001)</p>	<p><u>§ 131 - Abuse of human embryo or foetus</u> A person who creates a human embryo or foetus <i>in vitro</i> without the intention to transfer the embryo of foetus to a woman, or outside an institution duly authorised by law [...] shall be punished by a pecuniary punishment.”</p> <p>Comment: Embryo creation for research cloning purpose is explicitly prohibited but there is no provision on the use of existing <i>in vitro</i> embryo for research.</p>
<p>Finland*</p>	<p>Act on Medical Research, nº488/1999 of 1 November 1999 as amended by law nº295 of 29 April 2004 and entered in force on 1 May 2004</p>	<p><u>Section 13:</u> [...] Embryos that have been used for research may not be implanted in a human body.</p> <p><u>Section 26</u> Any person who undertakes research with the aim of : cloning human beings [...] Shall be fined or imprisoned for a period not exceeding two years for unlawful intervention on the genome.</p>	<p><i>IDEM</i></p>	<p><u>Section 11:</u> Research on embryos outside a woman's body may be carried out only by agencies that have been granted the appropriate licence by the National Authority for Medicolegal Affairs [...] Medical research shall be permitted on embryos only if no more than 14 days have passed from their formation.</p> <p><u>Section 13:</u> The production of embryos exclusively for the purpose of research shall be forbidden. [...]</p> <p><u>Section 25:</u> Any person who conducts research on embryos without the licence referred to in section 11 or in contravention of the restrictions laid down in sections 11 and 13 [...] shall be fined or imprisoned for a period not exceeding a year for <i>unlawful research on embryos and gametes.</i>”</p>

<p>France*</p>	<p>"Bioethics" law of 8 July 2004 amending law of 29 July 1994, included in Civil, Penal and public health codes</p>	<p><u>Civil code article 16-4:</u> Any attempt to give birth to a person genetically identical to another person, dead or alive, shall be forbidden.</p> <p><u>Penal code article 214-2:</u> Human reproductive cloning is qualified as a "crime against the human species". It is punished by a 7.500.000 Euros fine and a 30 years imprisonment penalty.</p>	<p><i>IDEM</i></p>	<p><u>Article L2151-5 of public health code:</u> By principle, research on human embryos is forbidden. Nonetheless, during a period of five years (2004-2009), research on embryos and on embryonic stemcells is allowed under strict conditions. It is controlled by the Biomedicine agency which delivers authorizations for intending such research and importing stemcells lines.</p> <p>The law only allows for research on embryonic stem cell lines derived from human embryos conceived in the context of medically assisted procreation.</p>
<p>Georgia</p>	<p>Law on Healthcare of 10 December 1997</p>	<p><u>Section 142 1):</u> Human cloning through the use of genetic engineering shall be prohibited.</p>	<p><i>IDEM</i></p>	<p>The ban set in force by section 142 1) of the Georgian Law on Healthcare prohibits research on human therapeutic cloning in so far the law doesn't differentiate the different cloning purposes.</p>
<p>Germany*</p>	<p>The Embryo Protection Act of 13 December 1990</p>	<p><u>Section 6:</u> (1) Anyone who causes artificially a human embryo to develop with the same genetic information as another embryo, foetus, human being or deceased person will be punished with imprisonment up to five years or a fine.</p>	<p><i>IDEM</i></p> <p>"Stemcells Act" of 28 June 2002 amended on 11 April 2008</p> <p>The Stemcells Act contains regulation on research to which the cloning ban pursuant to Section 6 of the Embryo Protection Act applies.</p>	<p><u>Section 6:</u> (1) Anyone who causes artificially a human embryo to develop with the same genetic information as another embryo, foetus, human being or deceased person will be punished with imprisonment up to five years or a fine (2) Likewise anyone will be punished who transfers into a woman an embryo designated in paragraph 1. (3) Any attempt is punishable.</p> <p><u>Section 7:</u> It is prohibited 1) to unite embryos with different genetic material to a cell conglomerate using at least one human embryo or 2) to join a human embryo with a cell that contains genetic information different from the embryo cells and induces them further to develop, or [...] Any violation will be punished with imprisonment up to five years or a fine.</p> <p><u>Section 4:</u> (1) The importation and utilization of embryonic stem cells shall be prohibited (2) Notwithstanding paragraph 1, the importation and utilization of embryonic stem cells for research purposes shall be permissible under the conditions stipulated in section 6 if: [...] a) The embryonic stem cells were derived before 1 May 2007.</p> <p>Comment: As exposed in Section 3 of the Act, embryonic stem cells only refers to all pluripotent stem cells derived from embryos which have been produced in vitro and</p>

				have not been used to induce pregnancy or which have been taken from a woman before completion of nidation. Embryos obtained by somatic cell nuclear transfer cannot be used for stem cells research.
Greece	Law n°3089 on medically assisted reproduction of 23 December 2002 Law 3305/2005 for the Implementation of medically assisted reproduction	<u>Article 1455:</u> Human reproduction with the methods of cloning is prohibited. <u>Article 2.3</u> (same provisions than above)	<i>IDEM</i> Law 3305/2005 for the Implementation of medically assisted reproduction	<u>Article 1459:</u> Persons resorting to assisted reproduction should decide in common [...] whether any cryo-preserved reproductive material that is not going to be used for their own treatment (surplus): [...] b) should be used for research or therapeutic purposes <u>Article 11 and 12</u> (same provisions than above)
Hungary*	Criminal Code, No. IV of 1978 as amended Law n°154 on public health of 15 December 1997	<u>Section 173/G:</u> (1) Any person who creates genetically equivalent human species during experimental research or during a medical procedure commits a felony offense and shall be punishable with imprisonment between five to ten years. [...] <u>Section 162:</u> Genetic research cannot be conducted if the research [...] aims to create a new human being. <u>Section 180:</u> Embryo cannot be used for the purposes of creating more embryos or for the purposes of changing the characteristics formed with the conception, nor is allowed to create genetically identical beings.	<i>IDEM</i>	<u>Section 173/E:</u> (1) Any person who performs a medical experiment on human embryo or gamete without, or in deviation of the license prescribed in the Act on Health Care, or creates a human embryo for scientific purposes, commits a felony offense and shall be punishable with imprisonment of up to five years. <u>Section 180</u> (3) Embryos shall not be brought into existence for research purposes; research shall be conducted only on embryos brought about for reproductive purposes when this is authorized by the persons authorized to decide upon its disposal, or when the embryo is damaged. <u>Section 182</u> (3) It is forbidden to separate the cells of the embryo unless it is necessary to determine the illness of the child to be born. Comment: Legislation on stemcells research is contradictory: Research on embryos is allowed even though stemcells research seems to be forbidden by the prohibition of separating cells from the embryos.
Iceland*	Artificial Fertilization Act, n°55, of 29 May 1996	<u>Article 12:</u> It is prohibited to: [...] d) perform cloning. <u>Article 14:</u> Violation of the provisions of this Act or of rules based on it entails fines or imprisonment of up to three months under the terms of this Act.	<i>IDEM</i>	<u>Article 11:</u> All research, experiments and operations on embryos is prohibited. Nevertheless, it is permitted to carry out research on embryos: a) if it is part of an <i>in vitro</i> fertilization treatment, b) if the intention is to diagnose hereditary diseases in the embryos themselves, c) if the purpose is to advance the treatment of infertility, or d) if the purpose is to improve understanding of the causes of congenital diseases and miscarriages.

				<p><u>Article 12:</u> It is prohibited to:</p> <ul style="list-style-type: none"> a) cultivate or produce embryos solely for research purposes, b) cultivate embryos for more than 14 days outside the body or once the primitive streak has appeared, c) transplant human embryos into animals [...] <p>Comment: Amendments to the original law provide opportunities, tough with limitations, for research on excess embryos from IVF procedures, including stem cells research and nuclear transfer for research purposes.</p>
Ireland**	Constitution of Ireland enacted on 1 July 1937 (Article 40 3° has been incorporated in the constitution in 1983)	<p><u>Article 40 3):</u> 3° The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.</p> <p>Comment: There is no specific regulation on reproductive cloning in Ireland. Nonetheless, the illegality of this practice is not contradicted.</p>	IDEM	<p>Comments:</p> <p>1° There is an actual controversy on the legality of stem cells research in Ireland. Some lawyers interpret the Constitution as prohibiting it while others interpret the word "unborn" as not including supernumerary embryos (out of a womb). A judgment of the High Court, <i>M.R. v T.R. & Ors</i>, 15 November 2006, stated that the term "unborn" is not applicable to frozen embryos. This judgment is currently on Appeal process to the Supreme Court.</p> <p>2° Stem cells research is currently processed in Ireland.</p> <p>3° There is a chronic debate on the embryo statute as abortion is prohibited considering that a human embryo shall be considered as a person according to the constitution.</p>
Israel*	The Prohibition of Genetic Intervention Law, 5759-1999, of 29 December 1998	<p><u>Section 1:</u> The purpose of this Law is to determine a prescribed period of five years [<i>until 2009 according to a five years extension decided by the Knesset assembly in March 2004</i>] during which no kind of genetic intervention shall be performed on human beings [...]</p> <p><u>Section 3:</u> [...] throughout the period during which the Law is in force, no person is to perform any act of intervention in the cells of any person for the purpose of human cloning.</p> <p><u>Section 6:</u> Any offence against this regulation is subject to imprisonment.</p>		<p>Comment: No provision forbids research on therapeutic cloning. Furthermore, Israel is involved in stem cells research and these researches are partially financed by the government.</p>
Italy*	Law n° 40/2004 on medically assisted reproduction entered in force on 24 February 2004	<p><u>Article 13. 3):</u> Are forbidden: [...] c) Cloning interventions [...] for reproduction or research purpose.</p>	IDEM	<p><u>Article 13.1):</u> Any experiment on human embryo is prohibited.</p> <p><u>Article 13. 2):</u> Clinical experimentation on human embryo is only possible for a therapeutic or a diagnostic purpose concerning the embryo's health itself.</p>

		<p><u>Article 13. 4):</u> A violation of the 1° is liable to a 2 to 6 years imprisonment penalty and a 50.000 to 150.000 Euros fine. A violation of 3° shall be more severe.</p>		<p>Comment: However, the law allows importing and working on embryonic stem cell lines produced before July 2001.</p> <p>A referendum occurred on 12 June 2005 asking whether limitations to research on embryos and provisions on human embryo status had to be abrogated. The referendum failed because of an insufficient vote number.</p>
Japan*	Law regulating the technique of human cloning and other similar techniques of 30 November 2000	<p><u>Article 3:</u> No person shall transfer a human somatic clone embryo, a human-animal amphimictic embryo, a human-animal hybrid embryo or a human-animal chimeric embryo into a uterus of a human or an animal.</p> <p><u>Article 16:</u> A person who has violated the provisions under Article 3 shall be punished with imprisonment for not more than ten years or a fine of not more than ten million yen, or with both of these penalties cumulatively.</p> <p>Comment: Article 1 defines the purpose of the law as well as some technical expressions employed. In this article, amphimictic is an individual which cannot be clearly assimilated to a human being or an animal.</p>	<i>IDEM</i>	<p><u>Article 1:</u> Based upon these understandings, the purpose of this law is [...] to regulate artificial creation of individuals similar to such individuals set forth herein [...] by means of taking other necessary measures to secure appropriate handling of such embryos.</p> <p>Comment: The law states about "specified embryos" which are embryos complying with the guidelines set by the minister of sciences and technologies in order to ensure the respect of ethics principles upon research on embryos. Example: Any Specified Embryo shall be handled in accordance with the Guidelines (article 5). Research cloning is therefore permitted.</p>
Kosovo*	Law n°2004 / 4 Kosovo Health Act of 20 August 2004	<p><u>Section 111:</u> Human cloning is forbidden.</p> <p>Comment: No specific penalty on human reproductive cloning has been set however it should be considered as a violation of ethical principles punishable by a 500 to 1000 Euros fine (section 119.3 d).</p>	<i>IDEM</i>	<p>Comment: No legal frame on research cloning and therapeutic cloning is set up by this law. Nonetheless, <u>section 106</u> states that: "Issues related to research on humans shall be defined with a special law".</p>
Latvia	Law on Sexual and Reproductive Health of January 2002	Section 16 of this law prohibits human reproductive cloning.	<i>IDEM</i>	<p>Section 16 of this law also prohibits the creation of embryo for both research and therapeutic purposes.</p> <p>Comment: If the creation of embryos for research or therapeutic purposes is forbidden, no provision sets any prohibition upon the use of supernumerary embryos for such purposes.</p>
Lebanon			Draft Law in relation to Assisted Human Reproductive techniques	<p><u>Article 8:</u> It is prohibited to use embryos for commercial or research purposes or to carry out genetic manipulations to the embryo.</p>

				<p><u>Article 12:</u> Any person who violates article 7, 8 or 10 of the present law shall be penalized by imprisonment [...] and by payment of a fine [...].</p>
Lithuania	Law n°VIII-1679 on ethics of biomedical research dated on 11 May 2000	<p><u>Section 3.3:</u> Cloning of human being shall be prohibited.</p> <p><u>Section 18:</u> Persons in breach of the requirements of this law shall be held liable in the manner provided by the law.</p>	<i>IDEM</i>	<p><u>Article 3.2:</u> Human embryos may be subjected only to clinical observations (non-invasive investigations). Other clinical investigations involving human embryos and their creation for purposes of biomedical research shall be prohibited. Human embryos may be subjected to such biomedical risks if they are not disproportionate to the potential benefit.</p> <p>Comment: Stemcells research is therefore prohibited.</p>
Mexico*	Mexico's Federal District Penal Code (local legislation).	<p><u>Section 154:</u> Is liable to a 2 to 6 years imprisonment sentence and a ban on public employment any person who: [...] iii) Creates human beings by cloning or performs genetic engineering with illicit purposes</p> <p>Comment: This is a local regulation only concerning Mexico's district. Nonetheless, some federal regulations are interpreted by Mexican lawyers as banning human reproductive cloning such as the General Health Law (1984) and its regulation on the sanitary control of organs, tissues and human cadavers (1986) as well as its regulation on scientific research (1987).</p>	National Institutes of Health Amendment Act dated of 20 July 2004	This Act created the National Institute of Genomic Medicine (INMEGEN) which has been authorized by lawmakers to undertake research on stemcells. This is an implicit recognition of research cloning.
Netherlands*	The Embryos Act entered in force on 1 September 2002.	<p><u>Section 24:</u> The following procedures are prohibited: [...] f. performing procedures with gametes or embryos with a view to the birth of a genetically identical human individuals;</p> <p><u>Section 28:</u> 1. Any person who acts in contravention of a prohibition contained in Section [...24...] whether intentionally or unintentionally, shall be liable to a prison sentence not exceeding one year or a fourth-category fine.</p>	<i>IDEM</i>	<p><u>Section 24:</u> The following procedures are prohibited: a. creating an embryo specifically for research purposes or for purposes other than the induction of a pregnancy and using such an embryo in research or for purposes other than the induction of a pregnancy; [...]</p> <p>BUT: <u>Section 33</u> indicates that <u>Section 24 (a)</u> shall lapse on a date to be determined by Royal Decree and that on the determined date, <u>Section 11</u> shall enter into force.</p> <p><u>Section 11:</u> Carrying out research with embryos created specifically for this purpose is prohibited. This prohibition shall not apply to research which is reasonably likely to lead to new insights in the fields of infertility, artificial reproduction techniques, hereditary or congenital diseases or transplant medicine, and which can only be</p>

				<p>performed by making use of embryos as referred to in the first sentence.</p> <p>Comment: The moratorium under Section 24(a) was supposed to expire, after 5 years, in 2007. However, a proposal was presented to renew the prohibition for 5 years by amending the Act.</p>
New Zealand*	<p>The Human Assisted Reproductive Technology Act (N°92/2004) of 10 November 2004 as amended by the Human Assisted Reproductive Technology Amendment Act (n°63/2007) of 19 September 2007</p>	<p><u>Schedule 1: FIRST Prohibited actions</u> 1) Artificially form, for reproductive purposes, a cloned embryo [...]. 3) Implant into a human being a cloned embryo. [...] 9) Implant into a human being gametes derived from a foetus, or an embryo that has been formed from a gamete or gametes derived from a foetus.</p> <p><u>Section 8:</u> (1) Every person commits an offence who takes an action described in Schedule 1. [...] (4) A person who commits an offence against this section is liable on conviction on indictment to imprisonment for a term not exceeding 5 years or a fine not exceeding \$200,000, or both.</p>	<i>IDEM</i>	<p>Research on stemcells is not prohibited by the law which gives the authority to advisory boards in cooperation with the Ministry of Health to edit guidelines on this issue. These guidelines have been adopted in September 2006 by the Ministry of Health authorizing the use of established stemcells for research even if the use of IVF (in vitro fertilized) embryos is prohibited.</p> <p>Comment: The law sets some restrictions as the prohibition to develop an in vitro embryo after 14 days or the storage of such embryos for more than 10 years. It also sets conditions on the acquisition of embryos from donors or import. Any violation shall be liable to imprisonment penalties and/or fines.</p>
Norway*	<p>Act of 5 December 2003 N° 100 on the application of biotechnology in human medicine as amended by law n°31 of 15 June 2007</p>	<p><u>Paragraph 3-5: Ban on the creation of human embryos through the use of cloning techniques</u> It is forbidden: a) to create human embryos the use of cloning</p> <p><u>Paragraph 7-5. Penal provisions</u> Whoever wilfully contravenes to this Act or provisions laid down pursuant thereto is liable to fines or to a term of imprisonment not exceeding three months. An accomplice is liable to the same penalties.</p>	<i>IDEM</i>	<p><u>Paragraph 3-1: Use of supernumerary fertilized eggs for research</u> Supernumerary eggs and cells originating from supernumerary fertilized eggs can only be used in research when the purpose is: [...] 3. to develop new knowledge for the purpose of future treatment of serious diseases in humans.</p>
Panama*	<p>Penal code, introduced by law n°14 of 18 May 2007 and its modifications introduced by Law 26 of 2008)</p> <p>Law n°3 prohibiting all forms of cloning and stating other provisions of 15 January 2004</p>	<p><u>Article 145</u> Anyone who fecundates human ova with a distinct aim than procreation will be sanctioned from six to ten years of prison. This sanction can increase up to half of the maximum punishment for using genetic manipulation to create identical human being by means of cloning or any other procedure.</p> <p><u>Article 1:</u> All kind of promotion, financing or donation as well as the use of public or private funds to experiments, investigate and perform any form of cloning a human beings, meaning</p>	<p>Familial code article 489 issued by law n°3 of 17 May 1994</p> <p><i>IDEM</i></p>	<p><u>Article 489:</u> Every minor has the right to: 1. His prenatal protection.</p> <p>Comment: An embryo is interpreted as a human beings</p> <p><u>Article 2:</u> Without prejudice to the previous article, it is allowed to reproduce tissues to repair organs in a therapeutic view, for prevention and to cure diseases, by using</p>

		<p>the creation of an embryo being the biological duplication of a human beings based on his DNA structure, is forbidden.</p> <p><u>Article 3:</u> Whoever violate the provisions of this law will be sanctioned to a 1.000.000 Balboas fine (1000\$).</p>		<p>umbilical cord of birth babies or by any mean or method that could be developed, only in his favour, in his family's favour or in a third party's benefit.[...] Tissues reproduction is allowed as long as it doesn't imply to create a human beings and it is out of lucrative interests for the person who grant his consent.</p>
Peru*	<p>Children and Adolescents Rights Code</p> <p>General Health Law n°26842 of 9 July 1997</p> <p>Criminal Code of Peru as amended by law n°27636 published on 16 January 2002</p>	<p><u>Article 1:</u> Is considered as a child any human beings from its conception to 12 years old [...]. The State protects those conceived (children) for everything that is benefitting to them [...].</p> <p><u>Article 7:</u> [...] The fertilization of human oocytes for purposes other than procreation shall be prohibited, as shall the cloning of human beings.</p> <p><u>Article 324:</u> Any person using any genetic manipulation technique to clone human beings shall be liable to a 6 to 8 years imprisonment penalty and an incapacitation [...] (Incorporated by 16 January 2002 Amendment law).</p>	<i>IDEM</i>	<p>Considering the Constitution and the definition of the children as human beings until their conception and the general prohibition on human cloning, research and therapeutic cloning should also be considered illegal.</p>
Poland			<p>Act n°17 of 7 January 1993 on family planning, protection of the human foetus and admissible conditions for an abortion + Medical professions Act of 5 December 1996</p>	<p>According to article 1 of the Family Planning Act, the right to life is accorded to every human being including at the prenatal stage. Furthermore, in accordance with the Medical Professions Act, an unborn child cannot be part of a scientific experiment. Article 21 of this law, specifies that research on stem cells cannot be qualified as therapeutic research as it has no direct benefit for the subject of the experiment. Hence, research on embryos is prohibited even if no specific legislation has been set in force on this issue.</p> <p>Comment: There is no definition of embryonic stages in the Polish legislation even if penalties are heavier when the foetus has became capable of living outside the pregnant mother's body. Therefore any attempt to produce stem cell lines will be considered as an illegal abortion, as the embryo is destroyed, which is liable to 3 years of prison.</p>
Portugal*	<p>Law n°32/2006 on medically assisted procreation (MAP) of 26 July 2006</p>	<p><u>Article 7:</u> 1. Reproductive cloning is prohibited as it tends to create human beings genetically identical to another one.</p> <p><u>Article 36:</u> 1. The transfer in a womb of an embryo created by nuclear transfer, unless if this technique is used for MAP applications, is punished by 1 to 5 years of prison. 2. The same penalty is required for those who proceed to embryo transfer obtained by embryo splitting.</p>	<i>IDEM</i>	<p><u>Article 9:</u> 1. It is prohibited to create embryos by MAP in the deliberate view of its use in research. 2. Scientific research on embryos is nonetheless legal if performed with the purpose of prevention, diagnostic or embryo therapy, of improving MAP's techniques, constituting Stemcells banks for transplants or for any other therapeutic purpose.[...]</p>

				<p>Comment: Research cloning is only allowed on supernumerary or abnormal embryos from MAPs and genetic diagnostics. Any research attempt violating the legal provisions set by this law is punished by 1 to 5 years in prison (art. 40).</p>
<p>Republic of Korea*</p>	<p>The Bioethics and Safety Law n°7150 entered in force on 1 January 2005 as revised on 16 March 2008</p>	<p><u>Article 1:</u> 1. No one shall implant a somatic cell embryo clone into a uterus, maintain a cloned embryo within a uterus, or give birth when the pregnancy results from the act of implanting a somatic cell embryo clone into a uterus. 2. No one shall induce or assist in the activities defined in Article 11-1.</p> <p><u>Article 49:</u> 1. Anyone who, in violation of Article 1-1 implants a somatic cell embryo clone into a uterus, maintains a cloned embryo within a uterus, or gives birth when the pregnancy results from the act of implanting a somatic cell embryo clone into a uterus shall be sentenced to up to 10 years of imprisonment.</p>	<p><i>IDEM</i></p>	<p><u>Article 17:</u> Remaining Embryos that have passed the storage period outlined in Article 16 may be utilized for the following purposes, but only until the embryological primitive streaks appear in their developmental process: 1. To conduct research aimed at developing contraception and infertility treatments; 2. To conduct research aimed at curing rare or incurable diseases, as decreed by the President. 3. To conduct other research approved by the President after being reviewed by the Committee. However, in order to utilize a remaining embryo that has been stored for less than 5 years, a new consent, for this new purpose, is required from the Consenters.</p> <p>Comment: Research on stemcells was banned on 2005 because of fraudulent claims from Korean scientists. The National Bioethics Committee removed this ban on March 2007.</p>
<p>Russian Federation (outdated moratorium)</p>	<p>Federal Law on a temporary Ban on Human Cloning of April 2002</p>	<p>The law was prohibiting reproductive cloning as well as import/export of clone through a 5 years moratorium that expired in 2007. So far, this legislation has not been extended or renewed.</p>		
<p>Saudi Arabia**</p>	<p>Recommendation n°4/14/23 of the National Committee of Bio & Medical Ethics (NCBE)</p>	<p>Human cloning (reproductive and therapeutic) and any other unacceptable downstream practices associated with reproductive technology and for other purposes are strictly prohibited.</p>	<p><i>IDEM</i></p>	<p>Human cloning (reproductive and therapeutic) and any other unacceptable downstream practices associated with reproductive technology and for other purposes are strictly prohibited.</p>
<p>Singapore*</p>	<p>Human cloning and Other Prohibited Practices Act n°34 of 1 October 2004</p>	<p><u>Section 5:</u> No person shall place any human embryo clone in the body of a human or the body of an animal.</p> <p><u>Section 18:</u> Any person who contravenes section 5, 7, 8, 9, 10, 11, 12 or 13 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both.</p>	<p><i>IDEM</i></p>	<p><u>Section 7:</u> No person shall develop any human embryo that is created by a process other than the fertilization of a human egg by human sperm, for a period of more than 14 days excluding any period when the development of the embryo is suspended.</p> <p>Comment: Research cloning is allowed with embryos that are not "prohibited embryos" in accordance with this law and under the conditions set up by the Ethical Guidelines on Gene Technology.</p>

Slovakia*	Law n°277/1994 on Healthcare + Act n°576/2004 of 22 September 2004 on healthcare, healthcare-related services and on the amendment and supplementing of certain laws	<u>Paragraph 46a:</u> Any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited. Comment: The wording of the additional Protocol on the Prohibition of Cloning Human Beings of the European Convention on Biomedicine and Human Rights has been reproduced. This wording has been also reused in Act n°576/2004 of 22 September 2004.	<i>IDEM</i>	<u>Paragraph 26:</u> (10) It is not allowed to perform the research without medical indication on (a) a living foetus or an embryo,
	Penal code (Law N°140/1961 , as later amended by law n°300/2005)	<u>Penal code paragraph 246 a):</u> Any intervention aiming to create a human being in any stage of its formation, which is genetically identical to another human being whether living or dead is punished by imprisonment for 3 to 8 years, a financial penalty and the injunction of professional activities.		Comment: No specific regulation exist on therapeutic cloning even if the above mentioned provision forbids research cloning as it is not a research performed on medical indication for the embryo.
Slovenia**	Law on Biomedically assisted reproduction n°70/2000 of 8 August 2000	Section 33 of this law prohibits human reproductive cloning within the terms of Protocol n°1 to the European Convention on Biomedicine and Human Rights which has been ratified by this country.	<i>IDEM</i>	<u>Article 38:</u> Scientific research on [...] early embryos, created for the purposes of biomedically assisted fertilization is allowed exclusively for the purposes of protecting and improving human health and only when the research cannot be performed, with comparable effectiveness, on animal embryos or by other methods, [...] Comment: No regulation prohibits research cloning but therapeutic cloning which implies the creation of an embryo genetically identical to another is prohibited because of article 33 of this law.
South Africa*	National Health Act n°61 of 23 July 2004.	<u>Paragraph 57:</u> (1) A person may not: (a) manipulate any genetic material, including genetic material of human gametes, zygotes or embryos: or (b) engage in any activity, including nuclear transfer or embryo splitting, [...] (5) Any person who contravenes a provision of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.	<i>IDEM</i>	<u>Paragraph 57:</u> (2)The Minister may under such conditions as maybe prescribed, permit therapeutic cloning utilising adult or umbilical cord stem cells. (3) No person may import or export human zygotes or embryos without the prior written approval of the Minister. (4) The Minister may permit research on stem cells and zygotes which are not more than 14 day olds on a written application and if- (a) the applicant undertakes to document the research for record purposes: and (b) prior consent is obtained from the donor of such stem cells or zygotes.
Spain*	Law n°14 on assisted reproductive techniques of 23 May 2006	<u>Article 26: Infractions</u> c. Very serious infractions [...] 9. The practice of nuclear transfer within a reproductive purpose.	<i>IDEM</i>	Research cloning on supernumerary embryos is allowed under the terms of articles 15 and 16 on the use of pre-embryos for investigations and conservation and use of pre-embryos for investigations respectively.

	<p>Penal code, provision introduced by organic law n°15/2003 of 23 November 2003</p>	<p><u>Article 160:</u> 2. Whoever fertilizes a human egg for another purpose than human procreation will be punished by a penalty of 1 to 5 years imprisonment and a special incapacity for public or office employment for 6 to 10 years. 3. The same penalties are applied for the creation of identical human beings by cloning or other procedures directed at racial selection</p> <p>Comment: Originally, law n°35/1988 on assisted Human Reproduction prohibited human reproductive cloning in its article 20 paragraph 2B k) until organic law n°10/1 995 suppressed this provision. Then, organic law n°15/2 003 replaced this prohibition on Spanish penal code as above mentioned. These changes are the result of a Constitutional Court decision n°116/1999 of 16 June 1999. Finally, law n°35/1988 has been abrogated and replaced by law n°14/2006.</p>	<p>Law N° 14/2007 on biomedical research of 3 July 2007</p>	<p><u>Article 33: Procurement of embryonic cells</u> (1) The creation of human pre-embryos and embryos solely for experimental purposes shall be prohibited. (2) The use of any technique for obtaining human stem cells for therapeutic or research purposes, including the activation of oocytes through nuclear transfer, shall be permitted under the terms laid down in this Law, provided that it does not entail the creation of a pre-embryo or embryo solely for this purpose.</p> <p>Comment: Research cloning is allowed.</p>
<p>Sweden**</p>	<p>Law n° 115 on measures for the purposes of research or treatment in connection with fertilized human oocytes of 14 March 1991 as revised on 1 April 2005 (text not found in English)</p>	<p>Human reproductive cloning is explicitly prohibited in the 2005 version of the law.</p>	<p><i>IDEM</i></p>	<p>The law on 1 April 2005 authorized research on fertilized eggs for purposes other than IVF treatment and research on therapeutic cloning.</p>
<p>Switzerland *</p>	<p>Federal Law on Embryonic Stemcells Research of 19 December 2003 entered into force on 1 March 2005</p>	<p><u>Article 3:</u> It is forbidden: [...] c. To create a clone, a chimera or a hybrid (Article 36, al.1, law of 18 December 1998 on medically assisted procreation), to produce embryonic stemcells from a clone, a chimera or a hybrid, or to use their cells. [...] Is also forbidden; [...] d. To implant into a woman a supernumerary embryo used to produce stemcells. [...]</p> <p><u>Article 24:</u> Is liable to an imprisonment penalty whoever intentionally ; [...] b. Uses supernumerary embryos for a purpose other than the producing of stemcells.</p>	<p><i>IDEM</i></p>	<p><u>Article 3:</u> It is forbidden: [...] c. To create a clone [...], to produce embryonic stemcells from a clone [...].</p> <p><u>Article 12: Scientific and ethical requirements for research projects</u> A research project within embryonic stemcells are to be used can only be managed if: a. The project aims to acquire essential knowledge: 1. Aiming to diagnostic, to treat or to prevent serious human diseases, or [...] b. Equal value knowledge cannot be obtained by other means c. The project complies with scientific quality requirements; d. The project is acceptable in view with the ethical grounds</p> <p>Comment: This law deals as well with patent law, stemcells international exchanges, etc.</p>

<p>Tunisia*</p>	<p>Law n°2001-93 relative to the medicine of reproduction of 7 August 2001</p>	<p><u>Section 8:</u> Reproductive medicine by the mean of cloning techniques shall be strictly prohibited.</p> <p>Sanction: 5 years imprisonment and 10.000 dinars fine.</p>	<p>IDEM</p>	<p><u>Section 9:</u> The in vitro conception or by other means of human embryos, for studies, research or experiment purposes is forbidden.</p> <p><u>Section 11:</u> The freezing of gametes or embryos is allowed only for therapeutic purposes in view of assisting two members of a couple to procreate [...] gametes can be conserved for a maximum period of 5 years [...]. At this delay expiry [...] these gametes shall be destroyed and the embryos freezing shall be interrupted.</p> <p><u>Section 13:</u> A human embryo shall only be conceived in vitro or by other techniques in the frame reproductive medicine.</p> <p>Comment: These 3 provisions implicitly prohibit therapeutic cloning as mentioned by recommendation n°5 of the National Medical Ethics Committee.</p>
<p>Turkey**</p>	<p>Regulation on Centres for medically assisted procreation (<i>The Official Gazette</i>, 8 July 2005, n°25869)</p>	<p>Reproductive cloning is forbidden.</p>		
<p>Ukraine*</p>	<p>Law prohibiting human cloning for reproductive purposes of 14 December 2004</p>	<p><u>Section 1</u> Human cloning for reproductive purposes is prohibited.</p> <p><u>Section 4</u> Persons who violate this Law are liable to civil, administrative, or penal sanctions.</p>		
<p>United Kingdom**</p>	<p>Human Embryology & Fertilization Act of 1 November 1990 as amended by the Human Fertilization and Embryology Act 2008 (c.22)</p>	<p><u>Section 3: Prohibitions in connection with embryos</u></p> <p>(2) No person shall place in a woman</p> <p>(a) an embryo other than a permitted embryo (as defined by section 3ZA), or</p> <p>(b) any gametes other than permitted eggs or permitted sperm (as so defined)."</p> <p>Comment: Section 3ZA further defines what is meant by "permitted eggs", "permitted sperm" and "permitted embryos". It can be deduced from the dispositions that human reproductive cloning is not allowed in the United Kingdom.</p>	<p>IDEM</p>	<p>Schedule 2: <u>ACTIVITIES FOR WHICH LICENCES MAY BE GRANTED</u></p> <p><u>Paragraphe 3 :</u> <i>Licences for research</i> 3 (1) A licence under this paragraph may authorise any of the following— (a) bringing about the creation of embryos <i>in vitro</i>, and (b) keeping or using embryos, for the purposes of a project of research specified in the licence. [...]</p> <p>PURPOSES FOR WHICH ACTIVITIES MAY BE LICENSED UNDER PARAGRAPH 3</p> <p>3A [...] (2) The principal purposes are—</p>

				<p>(a) increasing knowledge about serious disease or other serious medical conditions,</p> <p>(b) developing treatments for serious disease or other serious medical conditions [...]</p> <p>Comment: Research cloning is allowed in the United Kingdom.</p>
United Arab Emirates**	Draft law on accreditation of fertilization centres (prepared in July 2007)	The draft law implicitly prohibits all forms of human cloning, because it prohibits the marketing of human oocytes, zygotes and sperm for research purposes. It also prohibits research on embryos even if they are no longer subject to a parental project.		The draft law implicitly prohibits all forms of human cloning, because it prohibits the marketing of human oocytes, zygotes and sperm for research purposes. It also prohibits research on embryos even if they are no longer subject to a parental project.
United States of America	FEDERAL LEGISLATION		<p>Public Law n°104-99 ("Dickey Amendment") of 1996</p> <p>Executive Order n°13505 Removing Barriers to Responsible Scientific Research Involving Human Stem Cells</p>	<p>Dickey amendment, passed under Clinton's presidency and renewed under Bush's presidency, prohibits the allowance of federal funding for:</p> <p>(1) the creation of a human embryo or embryos for research purposes; or</p> <p>(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on foetuses in utero [...].</p> <p><u>Section 2: Research</u> The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.</p> <p>Comment: This executive order revokes the presidential statement of August 9, 2001 that limited federal financing for stemcells research on 22 lines existing before 2001 and also set aside Executive order n°13435.</p>
	STATES LEGISLATION	<p>Regulations on reproductive cloning have only been issued by state governments. So far, the following 13 states have banned reproductive cloning explicitly: California, Arkansas, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, Rhode Island, New Jersey, North Dakota, South Dakota, and Virginia.</p>		<p><u>States banning therapeutic cloning and research destroying embryos:</u> Louisiana, Michigan, Minnesota, Arkansas, Indiana, Iowa, Michigan, North Dakota, South Dakota, and Virginia (because 'human being' was left undefined in the legislation).</p> <p><u>States without cloning legislation:</u> Alabama, Alaska, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Kansas, Kentucky, Maine, Minnesota, Mississippi, Montana, Nevada, New Mexico, New York, North Carolina, Oregon, South Carolina, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming</p> <p><u>States funding Stemcells research:</u> California (California Institute for Regenerative</p>

	<u>Rhode Island</u> : §23-16.4-1 to 4-4 <u>New Jersey</u> : §2C:11A-1, §26:2Z-2 <u>North Dakota</u> : §12.1-39 <u>South Dakota</u> : §34-14-27 <u>Virginia</u> : §32.1-162.32-2			Medicine), Connecticut (Connecticut Stem Cell Research Grants Program), Illinois (Illinois Regenerative Medicine Institute), Maryland (Maryland Stem Cell Research Fund), and New Jersey (The Stem Cell Institute of New Jersey and the New Jersey Stem Cell Research Grants Program).
Vietnam**	Government Decree banning human cloning and surrogacy of 12 February 2003	This ordinance prohibits human reproductive cloning.		

COMMENT:

Croatia, Moldova and Romania don't appear in Table 1 even though these States signed and ratified protocol N°1 of Oviedo's convention on human reproductive cloning prohibition. They should be therefore considered as countries having a legislation banning it.

Table 2: International Conventions

	OVIEDO CONVENTION[♦]	ADDITIONAL PROTOCOL TO THE OVIEDO CONVENTION[‡]	PACT OF SAN JOSE, COSTA RICA[▲]
<u>Source</u>	Council of Europe, Convention open to signature on 4 April 1997 at Oviedo, Spain, and entered into force on 1 December 1999, CETS No. 164.	Council of Europe, Additional Protocol open to signature at Paris on 12 January 1998, and entered into force 1 March 2001, CETS No. 168.	Inter-American Specialized Conference on Human Rights of 22 November 1969, entered in force on 18 July 1978
<u>Short title</u>	Convention on Human Rights and Biomedicine	Protocol n°1 to the Convention on Human Rights and Biomedicine	American Convention on Human Rights
<u>Long Title</u>	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine	Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings	<i>IDEM</i>
<u>Relevant provisions</u>	<p><u>Article 18 - Research on embryos in vitro</u></p> <p>[...]</p> <p>2. The creation of human embryos for research purposes is prohibited.</p>	<p><u>Article 1:</u></p> <p>1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited.</p> <p>2. For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set.</p>	<p><u>Article 1:</u></p> <p>2. For the purposes of this Convention, "person" means every human being</p> <p><u>Article 2:</u></p> <p>Where the exercise of any of the rights or freedoms referred to in Article 1 is not already ensured by legislative or other provisions, the States Parties undertake to adopt, in accordance with their constitutional processes and the provisions of this Convention, such legislative or other measures as may be necessary to give effect to those rights or freedoms.</p> <p><u>Article 4.1:</u></p> <p>1. Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life.</p> <p>This Convention sets as a principle (using the term "in general") the right to life from the conception. Therefore, countries which ratified it should be considered as banning research destructing embryos as well as therapeutic cloning. Nonetheless, the term "in general" can be interpreted otherwise as Mexico did to allow therapeutic cloning research.</p>
<u>Comment</u>		Croatia, Moldova and Romania don't appear in Table 1 even though these States signed and ratified protocol N°1 of Oviedo's convention on human reproductive cloning prohibition. They should be therefore considered as countries having a legislation banning it.	

♦ Countries having ratified the Convention: Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia Georgia Greece, Hungary, Iceland, Lithuania, Moldova, Norway, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Switzerland, Turkey

‡ Countries having ratified the Protocol: Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Georgia, Greece, Hungary, Iceland, Lithuania, Moldova, Portugal, Romania, Slovakia, Slovenia, Spain, Switzerland

▲ Countries having ratified the Pact: Argentina, Barbados, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominica, Ecuador, El Salvador, Grenada, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Dominican Republic, Suriname, Trinidad and Tobago, Uruguay, Venezuela

Main sources

- WHO - International Digest Of Health Legislation: - <http://www.who.int/idhl-rils/frame.cfm?language=english>
- HumGen International – Database – <http://www.humgen.umontreal.ca>
- Center for Genetics and Society - <http://www.geneticsandsociety.org/index.php>
- Global Lawyers and Physician - <http://www.glphr.org/>
- Oxford Journals - <http://humrep.oxfordjournals.org/>
- World Law Bulletin - <http://www.fas.org/sqp/othergov/wlb/index.html>
- European Commission – National Ethics Committees - http://ec.europa.eu/research/biosociety/bioethics/bioethics_ethics_en.htm
- Stem Cell policy - <http://www.mbbnet.umn.edu/scmap.html>
- Bionetonline - http://www.bionetonline.org/english/Content/sc_leg2.htm
- Connexions - <http://cnx.org/content/m14836/latest/>
- The Hinxtongroup - http://www.hinxtongroup.org/wp_am_exc.html
- DNApolicy - <http://www.dnapolicy.org/>
- WHO –Ethics and Health (Bioethics committees) - <http://www.dnapolicy.org/>
- Lexadin - <http://www.lexadin.nl/>
- Regulacion Juridicas de las Bioetecnologias - <http://www.biotech.bioetica.org/>
- Eureth.net - <http://eurethnet.kib.ki.se/Inline/links.htm>
- Americans to ban cloning - <http://www.cloninginformation.org/>
- UK Department of Health - <http://www.advisorybodies.doh.gov.uk/>
- The Human Future - <http://www.thehumanfuture.org/>
- Pew Forum Stem Cells - <http://pewforum.org/docs/?DocID=318>
- Baltic countries Stem Cells - <http://www.scanbalt.org/>
- Legislationline - <http://www.legislationline.org>
- National legislation sites, National parliament sites, National Health Departments sites, Ethics committees sites, Council of Europe, Organisation of American States, etc.