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The Human Microbiome and the Nagoya Protocol: A challenging implementation

Legal expert brief on behalf of the Swiss Federal Office for the Environment (FOEN)

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Executive Summary

The human microbiome includes all microorganisms that live in coexistence with their human host, on cellular tissue like the skin, stomach, intestine, respiratory tract and urogenital sinus. While these microorganisms contain genetic material and hence are genetic resources, it is unclear if the Nagoya Protocol applies to the human microbiome.

The draft for an updated EU Guidance document on compliance measures for users from the Nagoya Protocol stresses that the human microbiome represents genetic resources of non-human nature and should thus be considered separate from human genetic resources. The latter have been explicitly excluded from the framework of the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP).

Against this background, the draft EU Guidance distinguishes two scenarios: If the human microbiome is studied as a whole – *in situ* (i.e. in or on the body) or in samples – the respective EU Regulation does not apply. However, if a study is focused on an identified individual taxon isolated from a sample of human microbiota, the EU Regulation applies. This brief examines if the same approach could be appropriate and justifiable for the Swiss practice in implementing the Nagoya Protocol.

The human microbiome seems to be a «borderline case» for the application of the Nagoya Protocol. On the one hand, one could argue that the microbiome is necessary for the proper functioning of the human body, is an integral and indispensable part of a human being, and should therefore be excluded from the CBD/NP framework just like human genetic resources. Utilization of genetic resources from the human microbiome is more likely related to considerations of human health rather than biodiversity, which would also speak against an inclusion under the CBD/NP framework.

On the other hand, it is striking that the human microbiome does also encompass human pathogens which are themselves covered by the CBD/NP framework. Both benign and pathogenic microorganisms are often shared and transmitted between humans and animals, which makes it evident that the very same species of microorganisms can play an important role for both human health and biodiversity. By inference, this would mean that the human microbiome is in principle covered by the CBD/NP framework, at least as long as there is no specialized international access and benefit-sharing instrument that would prevail (Art. 4 Para. 4 NP).

Furthermore, the objective of compliance with domestic legislation (Art. 15 NP) as the main added value of the Protocol tends to give priority to how Nagoya Protocol parties deal with different categories of genetic resources including from the human microbiome. Nothing seems to prevent a party from claiming sovereign rights over benign or pathogenic microbiota found in a human medical sample taken with the prior informed consent of the patient, or in human or animal material of unknown origin.

The draft EU Guidance seems to have stricken a balance between the main competing arguments. Given the considerations made in this brief, such a «compromise solution» seems equally appropriate and justifiable for the Swiss practice in implementing the Nagoya Protocol. This seems even more the case with Switzerland being surrounded by European member states, and embedded in Europe via a dense network of bilateral agreements and economic ties, which suggest that regulations should be harmonized as much as possible.

Nevertheless, the very fact that humans are highly mobile, travelling between countries with differing access and benefit-sharing legislation, suggests that the bilateral and somewhat static approach of the Nagoya Protocol might not be the most adequate mechanism to deal with genetic resources stemming from the human microbiome. Instead, a «specialized international access and benefit-sharing instrument» (Art. 4 Para. 4 NP) or a «global multilateral benefit-sharing mechanism» (Art. 10 NP) might be more appropriate, potentially for all samples with genetic resources of human origin, and potentially under the World Health Organization (WHO) or the United Nations Educational, Scientific and Cultural Organization (UNESCO). Therefore, the solution outlined by the draft EU Guidance might only be a temporary one until the international community can agree on an approach that better corresponds with the opportunities and needs of modern science and technology.

1. Question

1

According to the contract of 12 and 28 September 2019, the author submits several legal expert briefs on matters related to the Nagoya Protocol. The present brief deals with the following topic:

- The Guidance document of the European Commission on the scope of application and core obligations of Regulation (EU) No 511/2014 on the compliance measures for users from the Nagoya Protocol (the EU Guidance[1]) is likely to be amended.[2] It is proposed that the updated EU Guidance will address the status of human microbiota under the Nagoya Protocol (NP[3]), and consequently the Convention on Biological Diversity (CBD[4]). Considering the scope and applicability of relevant multilateral agreements and other international instruments, is it justifiable that the Federal Office for the Environment adopts a similar policy with regard to the human microbiome under the Nagoya Protocol? Which grammatical, historical, systematic and teleological aspects need to be taken into account? Which are the publicly available positions of CBD/NP parties and other stakeholders in this context?
- This brief does not cover the extensive field of intellectual property, personality and human rights. For a general examination of the legal status of the human microbiome in the Swiss legal system, see the expertise by Alexandre Dosch and Dominique Sprumont (in French).[5]

2. Introduction

2

The Nagoya Protocol deals with the third objective of the Convention on Biological Diversity, the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. According to Art. 2 CBD, genetic resources are genetic material of actual or potential value, with genetic material being any material of plant, animal, microbial or other origin containing functional units of heredity. Art. 2 NP states that the terms defined in Art. 2 CBD shall apply to the Nagoya Protocol.

3

The human microbiome can be defined as all microorganisms – including bacteria, fungi, viruses, archaea and eukaryotic microbes – that live in coexistence with their human host, on cellular tissue like the skin, stomach, intestine, respiratory tract and urogenital sinus.[6] Microorganisms and humans very often live in a mutualistic – a mutually beneficial – relationship.[7] While these microorganisms contain genetic material and hence are genetic resources, their status under the Nagoya Protocol is unclear. In their draft for an updated Guidance, the European Commission has developed a differentiated approach with a view to a practical implementation (section 3). It shall be examined if the same approach could be appropriate and justifiable for Switzerland. This examination shall first consider that human genetic resources are excluded from the scope of the CBD and the Nagoya Protocol (section 4), before taking into account different interpretation methods and positions by stakeholders and commentators (section 5).

3. The approach in the European Union

4

The draft for an updated EU Guidance stresses that the human microbiome represents genetic resources of non-human nature and should thus be considered separate from human genetic resources. From the essential

1 OJ C 313, 27 August 2016.

2 Unpublished draft of 30 April 2020.

3 Nagoya Protocol of 29 October 2010 on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol; SR 0.451.432); the German and Italian translations have no legal force.

4 Convention of 5 June 1992 on Biological Diversity (CBD; SR 0.451.43); the German and Italian translations have no legal force.

5 DOSCH/SPRUMONT, Le statut juridique du microbiome humain, Neuchâtel 2019.

6 Cf. DOSCH/SPRUMONT, p. 15 (with further references).

7 For the evolution of science and terms in microbiology, see YOUNG, p. 27 ff.

and often mutualistic interaction between human microbiota and the human body, the draft concludes that special conditions must apply to their use under EU Regulation No 511/2014: As long as the human microbiome is studied as a whole – *in situ* (i.e. in or on the body) or in samples – the EU Regulation would not apply. But as soon as a study is focused on an identified individual taxon isolated from a sample of human microbiota, the EU Regulation would apply. This differentiation is attributed to the uniqueness and functionality of the human microbiome to each individual, and his or her right to grant prior personal consent, as opposed to an isolated taxon which is no longer deemed to represent the unique microbial composition characteristic of an individual human.

5

Against this background, the draft for an updated EU Guidance presents different case studies. The draft illustrates that studies would be out of scope of EU Regulation No 511/2014 if they focused on the identity and quantity of different gut microbiota in relation to mental health, or in relation to the existence of the same microbiota in the general environment of the tested individuals. However, within the scope of EU Regulation No 511/2014 would be research on specific isolated gut microbiota associated with mental health benefits, or a study testing an isolated gut bacterium for use in probiotics. By lack of a direct connection to a human host, any research and development on microbiota found in sewage samples would be considered to be in scope of the EU Regulation No 511/2014.

6

With regard to geographical scope and access, the draft for an updated EU Guidance argues that any sovereign rights over isolated components of the human microbiome are considered to belong to the country where the microbiota was sampled, which would generally be the country of residence of the person the microbiota stem from. Where microbiota are sampled from a person normally resident in another country, the original country could claim sovereign rights over the microbiota only if sampling takes place on entry into the second country as their composition is unlikely to have changed since crossing the border.

4. The exclusion of human genetic resources from the Nagoya Protocol

4.1. Wording of the CBD, the Nagoya Protocol, and related COP decisions

7

Neither CBD nor Nagoya Protocol mention human genetic resources. However, the second Conference of the Parties (COP) to the CBD in 1995 «reaffirm[ed] that human genetic resources are not included within the framework of the Convention.»[8] This decision was also based on a background report prepared by the CBD Secretariat as mandated by CBD COP 1, which stated that «from the history of its negotiation, it is clear that the Convention was not formulated with human genetic resources in mind.»[9]

8

This decision was confirmed by CBD COP 10, which, together with the adoption of the Nagoya Protocol, agreed that «without prejudice to the further consideration of this issue by the COP […], human genetic resources are not included within the framework of the Protocol.»[10]

4.2. Negotiation background

9

The exclusion of human genetic resources from the CBD and the Nagoya Protocol was not contentious. At CBD COP 2, there was no opposition to excluding human genetic resources from the framework of the CBD, apart from a call by two Oceania nations for a separate «protocol on rights relating to human genes.»[11] During the negotiation process for the Nagoya Protocol, there was «general agreement» that human genetic

8 UNEP/CBD/COP/DEC/II/11, Para. 2.

9 UNEP/CBD/COP/2/13, Para. 64.

10 UNEP/CBD/COP/DEC/X/1, Para. 5.

11 Cf. Earth Negotiations Bulletin (ENB), Vol. 9, No. 39, Summary Report on CBD COP 2: 6-17 November 1995, p. 6, available at https://enb.iisd.org/download/pdf/enb0939e.pdf (all online references in this brief were last accessed on 30 September 2020).

resources should be excluded from the Protocol.[12] However, some authors highlight that the decision of CBD COP 2 not to include human genetic resources in the definition of biological resources was based on very limited discussion.[13]

4.3. Later developments

10

After the confirmation at CBD COP 10 to exclude human genetic resources from the CBD/NP framework, this issue hasn't been tabled again at a COP. However, the relationship between biodiversity and human health has been addressed particularly by the latest CBD COPs 13 and 14, also with reference to the human microbiome (see points 18 and 19 below). These discussions have not questioned the exclusion of human genetic resources as decided by CBD COPs 2 and 10. It is only a minority of authors that argue that practicality considerations would necessitate the scope of the CBD to be expanded to include human genetic resources, claiming that the CBD is «qualified to be the central agency at the global level for the advance of broader benefit-sharing frameworks.»[14]

5. The status of the human microbiome under the Nagoya Protocol

11

When considering the approach of the draft for an updated EU Guidance for the implementation of the Nagoya Protocol in Switzerland, the status of the human microbiome under the Nagoya Protocol should be examined via the method of the Swiss legal system for the interpretation of legal provisions,[15] which means we must look at

- the wording of provisions and related decisions (grammatical interpretation; section 5.1)
- the background of negotiations and developments under the CBD and the Nagoya Protocol (historical interpretation; section 5.2)
- the relationship with other elements within the CBD framework and other multilateral fora (systematic interpretation; section 5.3), and
- the objective and purpose of the CBD and the Nagoya Protocol (teleological[16] interpretation; section 5.4).

12

Publicly available positions of stakeholders are weaved into the below considerations. However, it doesn't seem that any CBD/NP parties (other than the EU) have publicly commented on the status of the human microbiome under the CBD/NP framework so far. Many parties may implicitly apply their general access and benefit-sharing regulations to organisms from the human microbiome, but the author is not aware of any parties that would have explicitly legislated in this regard. Due to some overlap with the topic of digital sequence information, it can be expected that views on the inclusion or exclusion of the human microbiome correlate to some extent with the views on the inclusion or exclusion of digital sequence information under the CBD/NP framework.[17] There is overlap in the sense that the utilisation of microorganisms of the human microbiome would often occur via genetic sequence data.

12 Cf. Earth Negotiations Bulletin (ENB), Vol. 9, No. 416, Summary of the Sixth Meeting of the Working Group on Access and Benefit-sharing of the CBD: 21-25 January 2008, p. 3, available at https://enb.iisd.org/download/pdf/enb09416e.pdf.

13 Cf. CHATURVEDI ET AL., p. 160.

14 Cf. CHATURVEDI ET AL., p. 153.

15 Cf. HÄFELIN/HALLER/KELLER/THURNHERR, pp. 28 ff. (with further references).

16 *Telos (Greek) = objective/purpose*.

17 For these views, see https://www.cbd.int/dsi-gr/2019-2020/submissions and https://www.cbd.int/dsi-gr/2017-2018; for the applicability of the Nagoya Protocol to digital sequence information, see SOLLBERGER (with further references).

5.1. Grammatical interpretation

13

Microorganisms of the human microbiome are genetic resources (see point 3 above), but are they «human genetic resources»[18] excluded from the CBD/NP framework (see point 7 ff. above)? «Human» in this context can mean either «of human origin» or «of the human genome». If we refer to genetic resources «of human origin», it would exclude the human microbiome from the CBD/NP framework. However, if we refer to genetic resources «of the human genome», it would include the human microbiome under the CBD/NP framework, at least in principle.

14

The International Chamber of Commerce (ICC) argues that the «term ‹human› [...] must include all normal functions of the human organism, including cells that live in and on our bodies which are necessary for the proper functioning of the human body. The human microbiome is therefore an integral and indispensable part of a human being and should therefore be considered as human material.»[19] While there seems to be some merit in treating human material in a holistic manner, voices from literature are less pronounced: ZECH holds that «human gene» is an ambiguous term considering that units of heredity are often shared between species, and that symbiosis – different species being in a close and long-term biological interaction – is very common.[20] RHODES points out that «human genetic resources» is broader than «human genome».[21]

15

The discussion on the human microbiome is not dissimilar to the one held on human pathogens during the negotiations of the Nagoya Protocol.[22] Human pathogens could also be considered «of human origin», and yet they have been included under the Nagoya Protocol in principle, albeit with an appeal for special consideration (Art. 8 Para. b NP) and a reservation of «specialized international access and benefit-sharing instrument[s]» (Art. 4 Para. 4 NP).

16

As a first conclusion, it seems clear that from a grammatical perspective, the term «human genetic resources» is far too general and multifaceted to determine whether it should include or exclude the human microbiome.

5.2. Historical interpretation

17

While the exclusion of human genetic resources from the CBD and the Nagoya Protocol had never been contentious (see point 9 above), the topic of the human microbiome seems to have surfaced only recently in discussions under the CBD and the Nagoya Protocol, and more in a research-related rather than negotiation-based context.

18

In 2016, CBD COP 13 encouraged parties and stakeholders «to promote and support further research on health-biodiversity linkages and related socioeconomic considerations, including [...] on the linkages between the composition and diversity of the human microbiome, and biodiversity in the environment», and invited parties to «foster interchange between environmental microbes and the human microbiome [...] in urban planning, design, development and management».[23]

19

In 2018, CBD COP 14 recognised «the importance of the human microbiome for human health»; it requested the CBD Executive Secretary and invited the World Health Organization (WHO) and other members of the Inter-agency Liaison Group on Biodiversity and Health to collaborate and «to compile information on

18 For the concept of genetic resources under the Nagoya Protocol, see GREIBER ET AL., pp. 70 ff.; MORGERA/BUCK/TSIOUMANI, pp. 59 ff.

19 International Chamber of Commerce (ICC), submission on Implications of EU Regulation 511/2014 on Research on the Human Microbiome, 3 Sept 2018, http://www.labip.com/wp-content/uploads/2016/07/Practical-Implications-on-Research-on-the-Human-Microbiome.pdf.

20 ZECH, pp. 882 f.

21 RHODES, p. 271, fn. 11.

22 See in detail MORGERA/BUCK/TSIOUMANI, pp. 102 ff.

23 UNEP/CBD/COP/DEC/XIII/6, Para. 6.c and Annex Para. d.

relevant research, experiences and best practices on the microbiome and human health».[24] At a side event, participants discussed the Healthy Urban Microbiome Initiative and the assumption that biodiverse green spaces in urban environments foster a biodiverse human microbiome. Humans with healthy airway, gut and skin microbiomes tend to have reduced immune-related health disorders such as allergies, auto-immune and chronic inflammatory diseases.[25]

20
From developments under the CBD and the Nagoya Protocol alone, it is not possible to conclude if parties and stakeholders tend to include or exclude the human microbiome under the CBD/NP framework. However, health and biodiversity are treated as two different, yet closely interrelated sectors,[26] which would suggest that matters are best dealt with under the framework they are most closely related to (see point 24 below).

5.3. Systematic interpretation

21
In the context of the Nagoya Protocol, it is striking that the human microbiome does also encompass human pathogens. While the human microbiome is the general term referring to all microorganisms living in coexistence with their human host, human pathogens are a subset of microorganisms causing human disease. Microorganisms very often are a part of medical samples (such as tissue or swabs) or other biological samples, either intentionally or accidentally. Also, both benign and pathogenic microorganisms are often shared and transmitted between humans and animals.[27] Benign microbiota such as gut bacteria are shared particularly between humans and companion animals such as dogs.[28] It is not always easy to draw a line between pathogenic and benign microorganisms and their functions.[29] It seems that benign microorganisms can become pathogenic in certain circumstances.[30]

22
The sharing of microbiota between humans and animals make it evident that the very same species of microorganisms can play an important role for both human health and biodiversity. This was one of the major reasons why human pathogens were not excluded from the scope of the Nagoya Protocol, but were rather addressed via a clause requiring «special consideration […] for cases of present or imminent emergencies» (Art. 8 Para. b NP).[31] The same rationale would speak against excluding the human microbiome entirely from the scope of the Nagoya Protocol, at least as long as there is no specialized international access and benefit-sharing instrument that would prevail according to Art. 4 Para. 4 Nagoya Protocol. The argument that the personal human microbiome is essential for the proper functioning of human physiology as opposed to expanding pathogens that are the cause of its dysfunctioning,[32] cannot invalidate the fact that humans and (mainly) animals share certain benign microbiota species which therefore are relevant for both human health and biodiversity. Besides, microorganisms of the human microbiome can sometimes also exist *in situ* without being dependent on an immediate human, animal or plant host.

23
Another argument for the exclusion of the human microbiome from the scope of the Nagoya Protocol is that it would be unethical for any government to claim sovereign rights over such an important element of human physiology.[33] It could in fact violate basic human rights if a country was to claim sovereign rights over

24 UNEP/CBD/COP/DEC/14/4, Preambular Para. 11 and Para. 14.c; for the Liaison Group, see https://www.cbd.int/health/ilg-health.

25 See the report of the side event at https://enb.iisd.org/download/pdf/sd/enbplus200num46e.pdf and the website of the Initiative at https://www.humi.global.

26 This is underlined by the title of decision UNEP/CBD/COP/DEC/14/4, «Health and biodiversity», and Preambular Para. 3.

27 Cf. WILKE, pp. 127 f. and 131 f. A «human-animal» pathogen is called a zoonosis (e.g. avian or swine influenza viruses).

28 Cf. COELHO ET AL., pp. 4 f.; TRINH ET AL., pp. 2 f. (with further references).

29 Cf. WILKE, p. 131.

30 See e.g. KUMAMOTO ET AL.

31 Cf. WILKE, pp. 131 f.; MORGERA/BUCK/TSIOUMANI, pp. 102 ff.

32 Cf. ZECH, p. 884; International Chamber of Commerce (ICC), submission on Research on the Human Microbiome, fn. 19.

33 Cf. FLACH ET AL., p. 4; JOHANSEN, p. 3; Lactic Acid Bacteria Industrial Platform (LABIP), submission to the CBD Executive Secretary of 15 Nov 2017, https://www.cbd.int/abs/submissions/assessment/labip-en.pdf; International Chamber of Commerce (ICC), submission on Research on the Human Microbiome, fn. 19.

human genetic resources, which doesn't answer the very question if microbiota living in coexistence with their human host are to be considered human genetic resources.[34] However, nothing seems to prevent a country from claiming sovereign rights[35] over (benign or pathogenic) microbiota found in a human medical sample taken with the prior informed consent of the patient,[36] thereby respecting his or her personality rights.[37] Even less could a country be denied sovereign rights over microbiota of unidentifiable human or animal origin, e.g. isolated from effluents at a wastewater treatment plant.

24
With regard to Art. 4 Nagoya Protocol, one could argue that a specialized instrument for access to human microbiota and related benefit-sharing would be best placed under WHO. However, WHO is «a late entrant into the debate on access and benefit-sharing»,[38] and neither the International Health Regulations (IHR, 2005)[39] relating to public health emergencies of international concern nor the Pandemic Influenza Preparedness (PIP) Framework (2011)[40] for the sharing of influenza viruses and access to vaccines and other benefits apply to benign microorganisms of human origin. However, the effectiveness of IHR and PIP Framework imply that benefits from the utilisation of microorganisms of the human microbiome would best be shared under an instrument primarily focused on human health. This is because utilising such microorganisms would more often occur in a health-related research and development context, and less so in the context of conservation and sustainable use of biodiversity. While different instruments can apply simultaneously for different aspects of the same circumstances (e.g. one instrument for benefit-sharing and another instrument for patient rights), it might not be ideal if they belong to different frameworks (e.g. biodiversity vs. health).

25
Outside WHO, there are non-binding instruments applicable to human microbiota. The Declaration of Helsinki (1964)[41] on ethical principles for medical research involving human subjects, adopted and regularly amended by the World Medical Association (WMA), states that medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group, and that this group should benefit from the knowledge, practices or interventions that result from the research (Para. 20). The same principle is stated by Guideline 10 of the International Ethical Guidelines for Biomedical Research Involving Human Subjects (1982),[42] adopted and regularly updated by the Council for International Organizations of Medical Sciences (CIOMS). The Human Genome Organisation's Committee on Ethics, Law and Society (HUGO CELS),[43] in their Statement on Benefit-Sharing for genetic research (2000), goes further in stipulating that for profit-making endeavours, the general distribution of benefits should be the donation of a percentage (e.g. 1%-3%) of the net profits to the health care infrastructure or for vaccines, tests, drugs, and treatments, or to humanitarian efforts.[44]

26
The Universal Declaration on Bioethics and Human Rights (2005) under the United Nations Educational, Scientific and Cultural Organization (UNESCO)[45] addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings (Art. 1 Para. 1). Also non-binding, the Declaration states that any research or intervention must only be carried out with the prior, free, express and informed

34 Cf. ZECH, pp. 883 f.

35 Such a claim could be made based on explicit regulation or by interpretation of the general domestic CBD/NP implementation framework.

36 See the example of South Africa, quoted in CBD/DSI/AHTEG/2020/1/2, Para. 46.

37 DOSCH/SPRUMONT, p. 43, seem to disagree, arguing that the Nagoya Protocol should not apply, and defending that the patient is the only one who can transfer the right to his/her microbiome. However, they later admit that personality rights don't apply in cases where the «source person» of microbiotic species is not identifiable anymore, see pp. 50, 53, 57.

38 CHATURVEDI ET AL., p. 164.

39 Cf. https://www.who.int/ihr/en.

40 Cf. https://www.who.int/influenza/pip/en.

41 Cf. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects.

42 Cf. https://cioms.ch/publications/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2.

43 Cf. http://www.hugo-international.org/HUGO-CELS.

44 See for those instruments ANDANDA ET AL., pp. 33 ff.

45 Cf. https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights; ANDANDA ET AL., pp. 55 ff.

consent of the person concerned (Art. 6 Para. 2), and that additional agreement of the legal representatives of a group or community concerned may be sought (Art. 6 Para. 3). The Declaration advocates that benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries (Art. 15 Para. 1). The Organisation for Economic Co-Operation and Development (OECD) has developed Guidelines for Human Biobanks and Genetic Research Databases (2009)[46] which include principles and best practices for the access to human biological materials and data, and respective benefit-sharing.

27

There are also other government-led international fora outside the UN system which specifically deal with the access to and use of the human microbiome, such as the International Human Microbiome Consortium (IHMC), founded in 2008.[47] IHMC members are funders and principal investigators of human microbiome research programs, and the Consortium's overall aim is to generate a shared data resource from international projects made freely available to the global scientific community. For this purpose, IHMC members agree to discourage the filing of intellectual property claims on basic data produced by common projects.[48] Further, the pan-European Microbial Resource Research Infrastructure (MIRRI) was launched in 2012 and brings together more than 50 public biorepositories and research institutes which provide facilitated access to microorganisms for research, development and application to meet the needs of innovation in biotechnology.[49] MIRRI is committed to the Nagoya Protocol and has published its own Best Practice Manual on Access and Benefit Sharing which, however, does not explicitly address the status of strains originating from the human microbiome.[50]

28

It is fair to conclude that the governance of microbial genetic resources is underdeveloped,[51] at least at the level of public international law. However, Art. 4 Nagoya Protocol doesn't preclude non-binding instruments from being recognised as specialized international access and benefit-sharing instruments,[52] as it distinguishes between binding «agreements» (Paras. 1 and 2) and «instruments» in general (Paras. 3 and 4). Hence there could be circumstances where state and private actors live up to the provisions of the UNESCO Universal Declaration on Bioethics and Human Rights, which would mean the Nagoya Protocol doesn't apply. But then again, the Protocol would still prevail as the default mechanism in cases where existing ethical guidelines are not – or not sufficiently – implemented.[53] Non-binding ethical principles can also provide guidance for the governance of human microbial genetic resources more generally, as Art. 4 Para. 3 Nagoya Protocol refers to «ongoing work or practices under [other] international instruments and relevant international organizations». Some principles such as informed consent prior to involvement in medical research might even constitute customary international law if they are widely and consistently accepted as a practice, for example via a prerequisite for government funding of national and international clinical trials.[54]

29

From a systematic perspective, the interpretation leads to the conclusion that – in principle – the Nagoya Protocol also applies to the human microbiome. This conclusion is based on the equivalence with human pathogens, the ambiguity between benign and pathogenic microbiota, and the widespread overlaps with mainly animal biodiversity.

46 Cf. http://www.oecd.org/sti/emerging-tech/guidelines-for-human-biobanks-and-genetic-research-databases.htm.

47 Cf. http://www.human-microbiome.org/index.php?id=25.

48 See the discussion of IHMC as an «institutional model for a transnational research commons» by REICHMAN/UHLIR/DEDEURWAERDERE, pp. 415 ff. and 519 ff.

49 Cf. https://www.mirri.org/page/About_MIRRI; REICHMAN/UHLIR/DEDEURWAERDERE, pp. 541 ff.

50 Cf. https://www.mirri.org/Content/Videos/ABSbestpracticemanual.pdf.

51 RHODES, p. 263.

52 WILKE, p. 145.

53 For the application «by default» see MORGERA/BUCK/TSIOUMANI, p. 97.

54 Cf. ANDANDA ET AL., pp. 35, 60.

5.4. Teleological interpretation

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The CBD has three objectives: the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (Art. 1 CBD). The objective of the Nagoya Protocol focuses on the third objective of benefit-sharing, which shall contribute to the first two objectives of the CBD (Art. 1 NP). This connection between the three objectives of the CBD is underlined by Art. 9 Nagoya Protocol, which places an obligation on state parties to encourage users and providers to direct benefits arising from the utilization of genetic resources towards biodiversity conservation and sustainable use. This aims to ensure a coherent interpretation and integrative implementation of the three objectives of the CBD in the context of the Nagoya Protocol.[55]

31

It could be argued that research and development on the human microbiome and its components would in most cases have a sole focus on human health, and would not be related to biodiversity considerations. It is therefore questionable if such a utilization of genetic resources should be covered by the CBD and Nagoya Protocol considering what these instruments are intended to achieve. However, certain authors argue that research and development increasingly blur the lines between genetic resources of human and other origin, and that drug development was «already inextricably integrating the use of these resources [of different human, animal, plant and microbial origin] into the same discovery programmes», so that the scope of the CBD (and consequently the Nagoya Protocol) should be expanded to human genetic resources.[56] Others again argue that the bilateral transactional benefit-sharing approach of the CBD/NP has not yet generated substantial benefits for biodiversity conservation, and has not kept pace with the evolving practice of open access, transparency and free exchange within the scientific community; they advocate for a «new approach for ethically sharing the benefits of science and technology» altogether.[57]

32

Apart from the access and benefit-sharing principles already anchored in the CBD, it is the objective of compliance with domestic legislation (Art. 15 NP) which is newly introduced with the Nagoya Protocol as its «most far-reaching innovation».[58] If this objective is the main added value of the Protocol, it is crucial to consider how domestic legislation in Nagoya Protocol parties deals with different categories of genetic resources including from the human microbiome. If many parties include human microbiota under their access and benefit-sharing provisions, this could indicate that the Nagoya Protocol may well apply to the human microbiome.

33

The above glimpse of opposing views on what the CBD/NP should and could achieve, and the somewhat subjective argument regarding compliance with domestic legislation, illustrate that the teleological perspective does not lead to a clear conclusion whether the human microbiome should be covered by the Nagoya Protocol or not. As already concluded above (point 20), it might be best to deal with matters under the framework they are most closely related to, which for the human microbiome would be the WHO or UNESCO, where parties would yet have to agree on a legally binding regime.

55 Cf. MORGERA/BUCK/TSIOUMANI, p. 192; GREIBER ET AL., pp. 125 f.

56 Cf. CHATURVEDI ET AL., pp. 155, 166 f.

57 Cf. LAIRD ET AL., pp. 1200 ff.; REICHMAN/UHLIR/DEDEURWAERDERE argue that «missing in the [bilateral] approach [is] any recognition of, or provision for, the role and needs of public science and the culture collections as indispensable intermediaries between the providers of raw materials and the commercializers of end products»; also see FLACH ET AL., pp. 4 f., who recommend that a multilateral system and standardized material transfer agreement is established for the access to and use of lactic acid bacteria (ditto Lactic Acid Bacteria Industrial Platform [LABIP] submission, fn. 33).

58 GLOWKA/NORMAND, p. 34; also see BUCK/HAMILTON, pp. 52 ff.

6. Conclusions

34

The above considerations illustrate that the human microbiome may well be a «borderline case» for the application of the Nagoya Protocol, with good arguments speaking for and against its inclusion under the CBD/NP framework. The analogy with human genetic resources and the focus on human health issues would favour an exclusion, while the equivalence with human pathogens and the focus on organisms shared between species would suggest an inclusion. The respect of domestic access and benefit-sharing legislation and of sovereign rights to genetic resources as core objectives of the Nagoya Protocol also seem to speak for an inclusion in principle.

35

The draft for an updated EU Guidance seems to have stricken a balance between the main competing arguments, in that it excludes activities with the human microbiome as a whole from the EU Regulation implementing the Nagoya Protocol, but includes activities with identified individual taxa isolated from a sample of human microbiota. Given the considerations made in this brief, such a «compromise solution» seems equally appropriate and justifiable for the Swiss practice in implementing the Nagoya Protocol. This seems even more the case with Switzerland being surrounded by European member states, and embedded in Europe via a dense network of bilateral agreements and economic ties, which suggest that regulations should be harmonized as much as possible.

36

Nevertheless, the very fact that humans are highly mobile, travelling between countries with differing access and benefit-sharing legislation, suggests that the bilateral and somewhat static approach of the Nagoya Protocol might not be the most adequate mechanism to deal with genetic resources stemming from the human microbiome. Even though the special consideration of human health by Art. 8 Para. b NP opens a door towards «distributive justice to the benefit of those in need»,[59] it might be more appropriate to develop a «specialized international access and benefit-sharing instrument» (Art. 4 Para. 4 NP) or a «global multilateral benefit-sharing mechanism» (Art. 10 NP), potentially for all samples with genetic resources of human origin, and potentially under WHO or UNESCO. This again would suggest that the solution outlined by the draft EU Guidance is only a temporary one until the international community can agree on an approach that better corresponds with the opportunities and needs of modern science and technology.

59 WILKE, p. 147.

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