



S/1534/2017

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NOTE BY THE TECHNICAL SECRETARIAT**RESULTS OF THE SURVEY ON BIOMEDIATED PROCESSES**

1. Paragraph 1 of Part IX of the Verification Annex to the Chemical Weapons Convention (hereinafter “the Verification Annex”) requires declarations of other chemical production facilities (OCPFs) that produce by synthesis unscheduled discrete organic chemicals (DOCs)¹ over specified thresholds. The outstanding issue on the scope of the definition of “production by synthesis” under Part IX of the Verification Annex is whether the term includes biochemical and biologically mediated processes (hereinafter “biomediated processes”). For scheduled chemicals, the Conference of the States Parties (hereinafter “the Conference”) decided at its Second Session to include these processes in the definition of “production” (C-II/DEC.6, dated 5 December 1997). For unscheduled DOCs, the Conference at its Third Session referred the issue to the Scientific Advisory Board (SAB), in accordance with decision C-III/DEC.5 (dated 19 November 1998).
2. As discussed during consultations on chemical industry and other Article VI issues, to assess the impact of the SAB’s view that “any process designed for the formation of a chemical substance should be covered by the term ‘produced by synthesis’” (SAB-19/1, dated 12 September 2012 and RC-3/DG.1, dated 29 October 2012), the Technical Secretariat has conducted a survey (S/1436/2016, dated 14 November 2016). The objectives of the survey were to evaluate the number and the relevance to the Chemical Weapons Convention of plant sites that would become declarable if the SAB recommendation was broadly implemented.

Results

3. A total of 32 States Parties², from across all regional groups (Figure 1), responded to the survey, the extended deadline for which was 15 August 2017. Not all responses contained precise numbers of additional plant sites that could become declarable.

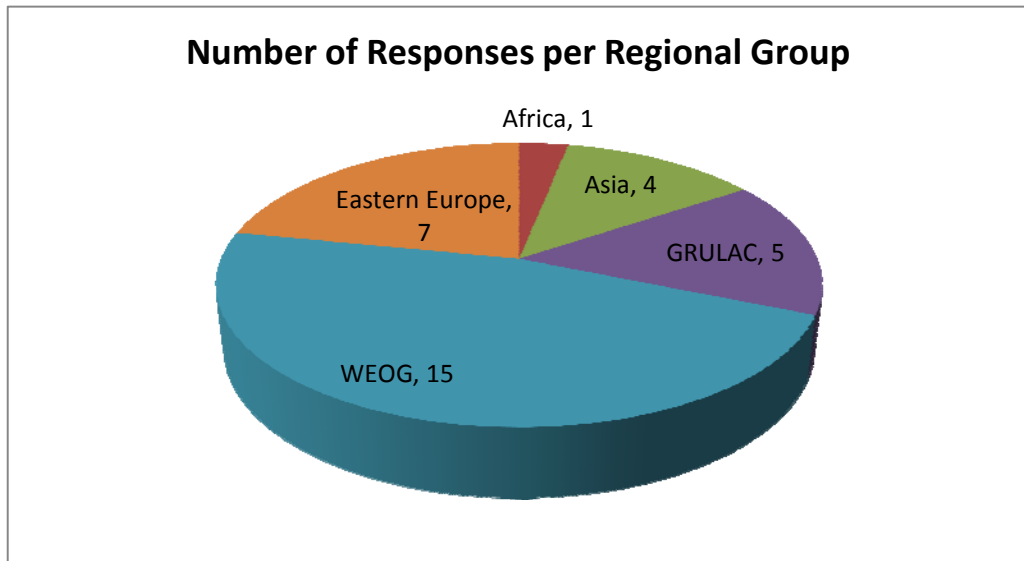
¹ In accordance with paragraph 4 of Part I of the Verification Annex, “‘Discrete Organic Chemical’ means any chemical belonging to the class of chemical compounds consisting of all compounds of carbon except for its oxides, sulfides and metal carbonates, identifiable by chemical name, by structural formula, if known, and by Chemical Abstracts Service registry number, if assigned”.

² Andorra, Argentina, Australia, Austria, Bangladesh, Belarus, Brazil, Burkina Faso, Canada, Chile, Costa Rica, Croatia, Cuba, the Czech Republic, France, Greece, Iran (Islamic Republic of), Ireland, Italy, Japan, the Netherlands, New Zealand, Portugal, the Russian Federation, Slovakia, Slovenia, Switzerland, Thailand, Turkey, the United Kingdom of Great Britain and Northern Ireland, the United States of America, and Uzbekistan.



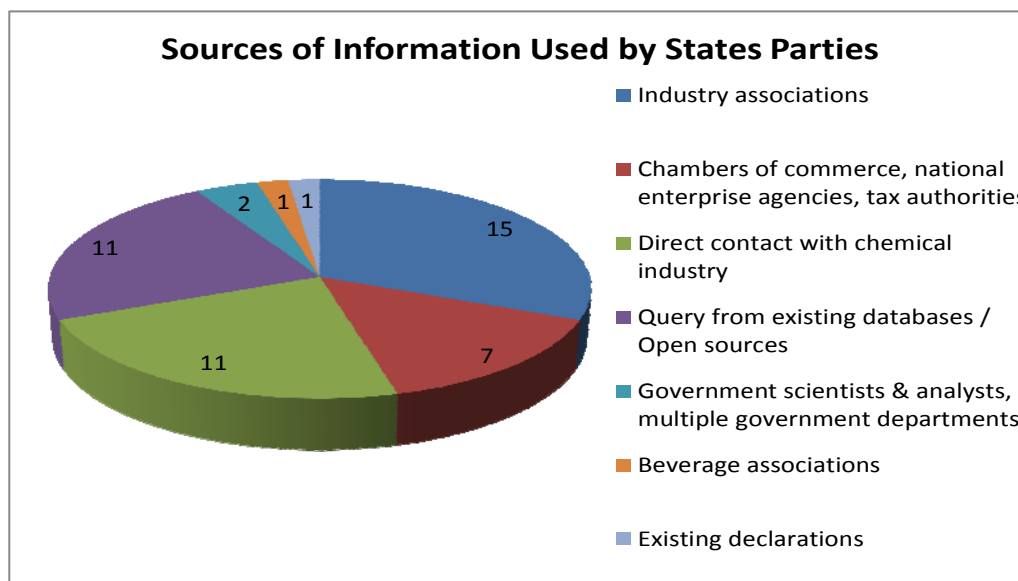
Furthermore, some National Authorities only provided their views on the topic without providing survey data.

FIGURE 1: NUMBER OF RESPONSES PER REGIONAL GROUP



4. Twenty-five States Parties provided information about the actions taken to conduct the survey. Several States Parties used multiple sources to obtain the data; the sources of data across all respondents are summarised in Figure 2. Most States Parties indicated that the survey was conducted through industry associations, chambers of commerce, national enterprise agencies, tax authorities, direct contact with chemical industry or by querying existing databases. Some States Parties also contacted governmental scientists and analysts across multiple departments, and beverage associations. For some of the States Parties that already declare biomediated processes, the data was compiled from existing declarations. Finally, some States Parties stated that companies producing alcohol by fermentation for human consumption, industrial scale bakeries, the dairy industry and industries that manufacture microorganisms (e.g. viruses and bacteria) were not included in the survey.

FIGURE 2: SOURCES OF INFORMATION USED BY STATES PARTIES

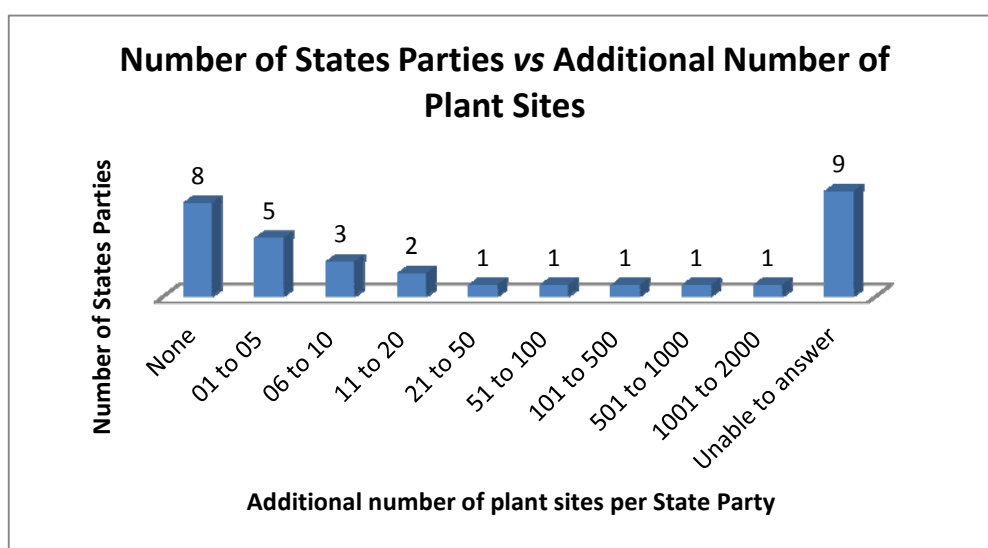


5. Twelve States Parties reported that, as a general policy, they already declare plant sites producing DOCs regardless of the type of process (e.g. States Parties currently declare facilities that produce chemicals by biochemical or biologically mediated processes) whereas 17 States Parties indicated they do not declare plant sites producing DOCs regardless of the type of process. Three States Parties did not answer this question. Key points from the responses were:
- The 12 States Parties whose policy is to declare plant sites producing DOCs regardless of the type of process stated that their regulations include facilities producing DOCs through chemical, biochemical or biological processes above the declaration thresholds. Nevertheless, four of them noted having certain exclusions for, inter alia, production of alcoholic beverages and processes that utilise biochemical processes within living organisms, such as fermentation. Finally, one State Party stated that proteins are not considered to be DOCs, while peptides with unique and stable amino acid chain length are considered to be DOCs.
 - The 17 States Parties whose policy is to not declare all plant sites producing DOCs regardless of the type of process have diverse views and practices. Some of these States Parties explained that their view of “production by synthesis” included only traditional chemical synthesis and, as such, their policy is to only declare plant sites that produce DOCs through this route. Other States Parties referenced regulatory mechanisms or national guidance that excludes from declaration DOCs or DOC mixtures produced by biomediated processes. Furthermore, some States Parties exempt from declaration plant sites exclusively producing materials by biochemical or biologically mediated processes designed for consumption by humans or animals. Finally, one State Party specified that its regulatory mechanism

defines DOCs as items classified under chapters 28 and 29 of the Harmonized System Code³ and that there are provisions excluding fermentation processes.

6. Different views were reported on the definition of biomediated production. Whereas some States Parties did not define biomediated production in their regulatory framework, others used the following criteria:
 - (a) Any single or multi-step chemical process that involves the use of biochemistry (e.g. enzymes as catalysts) or biology (e.g. bacteria, yeasts or fungi, tissue culture, viruses, or other life forms) to alter at least one chemical bond in (an) initial reactant(s), resulting in (a) new product(s).
 - (b) Examples of relevant biomediated processes included fermentation, biocatalysis, biotransformation, and anaerobic digestion. For some States Parties, the extraction of vegetable oils from plants would also be considered as biomediated process.
 - (c) Examples of chemicals produced by biomediated processes included amides, amino acids, lipids, organic acids, vitamins, pharmaceutical excipients, alcoholic beverages, and biofuels, which find applications in the pharmaceutical industry, the food and feed industry, and many other sectors.
7. The effect on OCPF declarations if biomediated processes were covered by the term “produced by synthesis” is illustrated in Figure 3. Eight States Parties reported no impact on their declarations, either because plant sites using biomediated processes are already declared or because no plant sites engage in biomediated processes (as defined by that State Party). Fifteen States Parties reported that additional plant sites would be declared. Nine States Parties were unable to provide a precise number of additional plant sites.

FIGURE 3: STATES PARTIES’ RESPONSES REGARDING ADDITIONAL NUMBER OF PLANT SITES

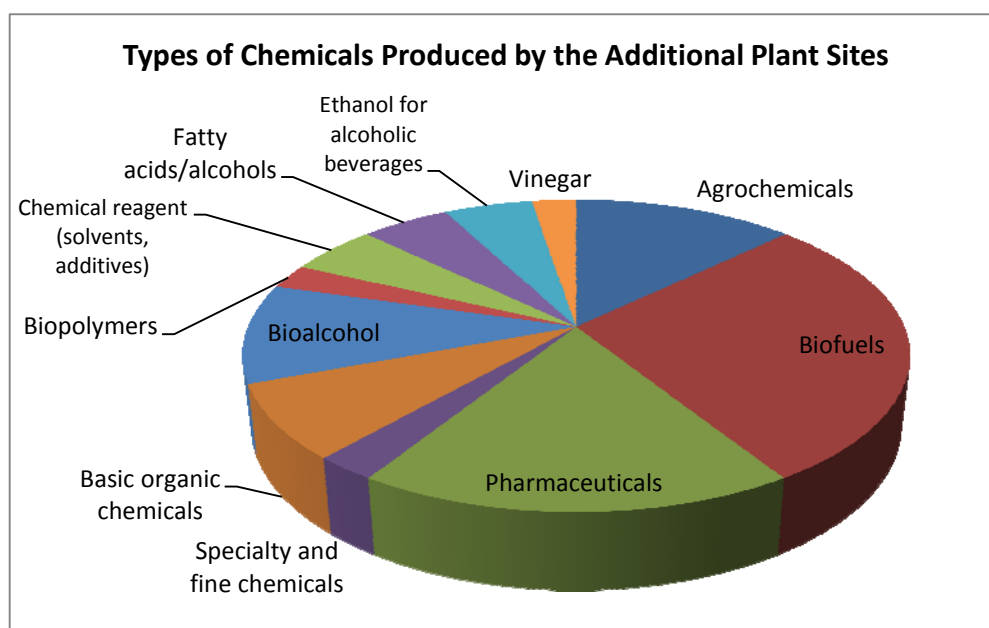


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As indicated by the World Customs Organization (<http://www.wcoomd.org/en.aspx>).

8. The types of chemicals produced by these additionally declared plant sites are summarised in Figure 4. As precise numbers of additional plant sites for each type of chemical were not provided by all of the responding States Parties, the results illustrated in Figure 4 represent the frequency with which the types of chemicals were reported. Biofuels represented the largest portion (reported by 11 States Parties), followed by pharmaceuticals (seven States Parties), agrochemicals (five States Parties), bioalcohol (four States Parties), and basic organic chemicals (three States Parties). Other reported classes of chemicals included biopolymers, chemical reagents (solvents and additives), fatty acids and fatty alcohols, ethanol for alcoholic beverages, and vinegar. There are examples of all the reported types of chemicals (except polymers) under current declaration practices.

FIGURE 4: TYPES OF CHEMICALS PRODUCED BY THE ADDITIONAL PLANT SITES



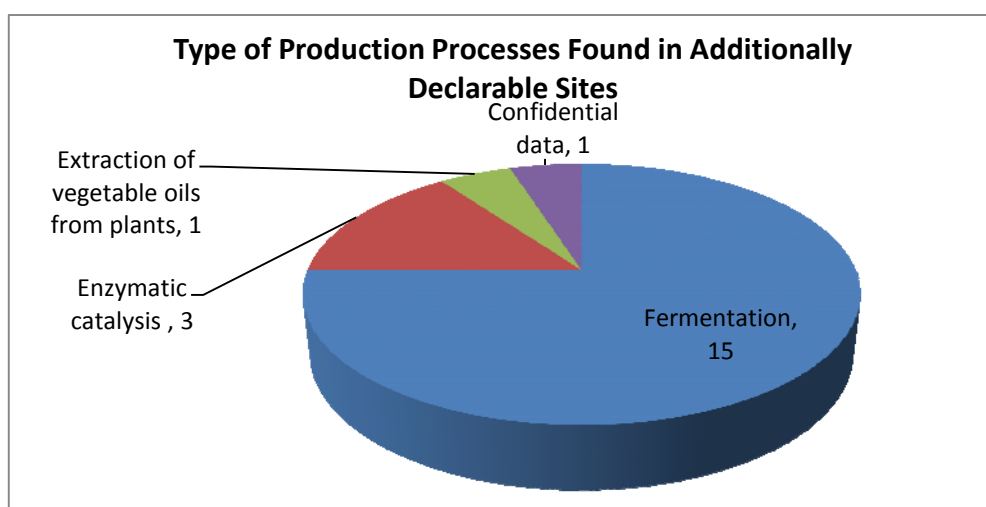
9. The intended uses of chemicals that would be produced at the additionally declared plant sites are summarised below based on approximate numbers received from survey responses. Human consumption as food and beverage represented the largest reported use. This was followed by ethanol for use as a biofuel and biofuels other than ethanol. Reported uses of ethanol other than as biofuel included the manufacture of perfumes, cosmetics, lye, fertilizer and herbicide. Other uses of chemicals included pharmaceuticals and chemicals used for medical purposes, cosmetics, production of organic chemicals, acetic acid for human consumption and food additives. If declarations excluded DOCs produced as food and beverage for human or animal consumption as well as biofuels, the total number of increased declarable plant sites would be approximately 60, as opposed to the 2,904 shown in Table 1 below.

TABLE 1: INTENDED USES OF CHEMICALS PRODUCED BY THE ADDITIONAL PLANT SITES

Intended Uses of Chemicals	Number of Additional OCPFs
Human consumption as food and beverage	2,904
Ethanol for use as a biofuel	112
Biofuels other than ethanol	70
Ethanol for other purpose	30
Pharmaceuticals/ medicines/ human health	23
Acetic acid for human consumption	4
Food additives	3
Production of other organic chemicals	3
Cosmetics	1

10. Figure 5 summarises which different types of biomediated production processes were found in the additionally declarable sites. The most common production process reported is fermentation, followed by enzymatic catalysis. One State Party also mentioned the extraction of vegetable oils from plants as a biomediated production process, and another did not specify an exact process as this was considered confidential information.

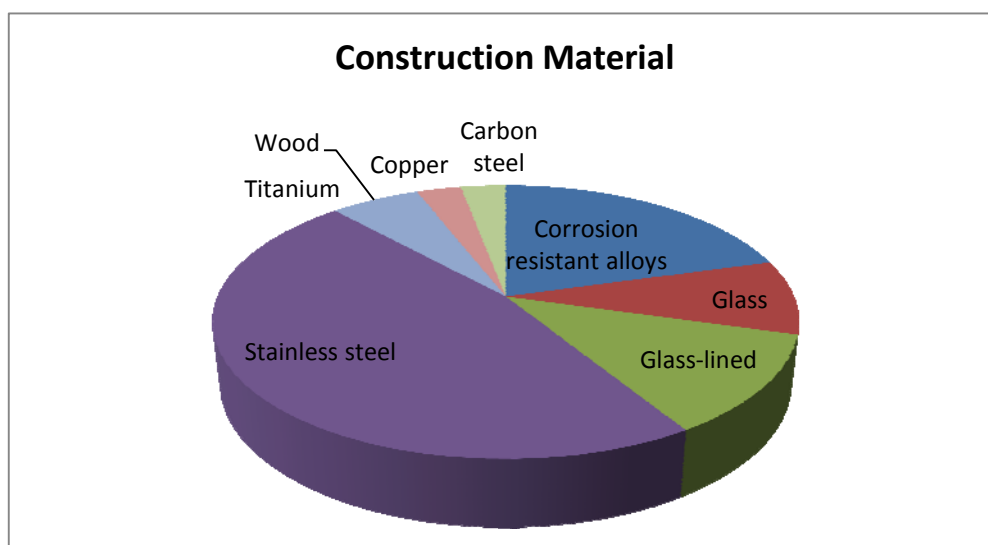
FIGURE 5: TYPE OF PRODUCTION PROCESSES FOUND IN ADDITIONALLY DECLARABLE SITES



11. Regarding the process configuration of the additional OCPFs, many States Parties reported plant sites that are dedicated to the production of a given DOC and can operate in batch or continuous modes. This would be consistent with facilities that produce alcoholic beverages, food, or biofuels. However, many of the respondents reported that they could not provide precise process configurations for the additional OCPFs. As described in EC-53/S/5 (dated 17 June 2008), multipurpose facilities operating in a batch mode are considered to be of higher relevance to the Convention, as those can more easily be converted to produce other chemicals, including scheduled chemicals.

12. The reported construction material of bioreactors and other relevant processing equipment used in the additional OCPFs is summarised in Figure 6. Stainless steel was the most commonly reported material (16 States Parties), followed by corrosion resistant alloys (seven States Parties), glass-lined (four States Parties), and glass material (three States Parties). Other reported materials included wood, titanium, copper and carbon steel. These types of materials are identical to the types of materials found in traditional chemical manufacturing processes. Six States Parties could not provide precise data regarding construction material of the bioreactors or other relevant processing equipment for the additional OCPFs.

FIGURE 6: CONSTRUCTION MATERIAL USED IN BIOREACTORS AND OTHER PRODUCTION EQUIPMENT FOR THE ADDITIONALLY DECLARABLE PLANT SITES



Conclusions

13. The survey indicates there is a divergence of views and practices across States Parties on implementation of the OCPF regime regarding biomediated processes. Approximately 40% of States Parties that replied to the survey already declare, as a general policy, plant sites producing DOCs regardless of the type of process (i.e. including facilities that produce chemicals by biomediated processes). However, some of these States Parties also have certain exclusions and do not declare production of alcoholic beverages and some specific biochemical processes such as fermentation. Furthermore, the survey showed that the States Parties that, as a general policy, do not declare plant sites producing DOCs, regardless of the type of process, also have divergent views and justifications for their approaches.
14. Table 2 below provides an estimate on the increased number of declarable facilities across the regions should the SAB recommendation be implemented with and without the exemptions of DOCs produced for food and beverage for human or animal consumption and biofuels. The largest potential impact would be for facilities producing ethanol for alcoholic beverages or biofuels; should these types of DOCs be given exclusions, the impact is expected to be small.

TABLE 2: NUMBER OF ESTIMATED INCREASE IN DECLARABLE FACILITIES WITH AND WITHOUT EXCLUSIONS FOR DOCS USED FOR FOOD, BEVERAGE AND BIOFUELS

Region	Number of Additional OCPFs	
	Without Exclusions	With Exclusions
Africa	1 to 5	1 to 5
Asia	100 to 500	1 to 5
Eastern Europe	1,001 to 2,000	21 to 50
GRULAC	21 to 50	1 to 5
WEOG	1,001 to 2,000	21 to 50

15. It is expected that some States Parties currently not submitting declarations under Part IX of the Verification Annex would be required to declare additional OCPFs, should the definition of “production by synthesis” include biomediated processes.
16. The results of this survey should inform further discussion in upcoming consultations on chemical industry and other Article VI issues.