

## 6 APPENDIX

Tables and figures that were not shown in the text above are listed below.

### 6.1 TABLES

Table 6-1 shows endotoxin recovery of radiated and non-radiated filter pieces. For detailed information see 2.2.4.4.

**TABLE 6-1 ENDOTOXIN ACTIVITY ON CO60- / NOT RADIATED FILTER PIECES**

| Type of Filter     | Recovered Endotoxin (EU) |              |
|--------------------|--------------------------|--------------|
|                    | Radiated                 | Non Radiated |
| Glass fiber        | 487.8                    | 770.4        |
|                    | 79.4                     | 586.8        |
|                    | 772.2                    | 547.2        |
|                    | 392.4                    | 540.0        |
|                    | 133.2                    | 612.0        |
| Synthetic<br>fiber | 153.0                    | 235.8        |
|                    | 415.8                    | 466.2        |
|                    | 37.8                     | 527.4        |
|                    | 50.4                     | 244.8        |
|                    | 181.8                    | 259.2        |
| Cellulose<br>fiber | 61.2                     | 37.8         |
|                    | 55.8                     | 64.8         |
|                    | 19.8                     | 19.8         |
|                    | 27.0                     | 1.8          |
|                    | 106.2                    | 1.8          |

For explanation please see Results 4.6.1.

**TABLE 6-2 ENDOTOXIN ACTIVITY IN PTTs WITH DIFFERENT CONTAMINATIONS AND EXTRACTION METHODS**

| Extraction procedure      | T/U/LPS 2,000 | T/S/LPS 2,000 | P/U/LPS 2,000 | P/S/LPS 2,000 |
|---------------------------|---------------|---------------|---------------|---------------|
| Mean                      | 739 EU        | 990.7 EU      | 1664.3 EU     | 2060 EU       |
| Standard error mean       | 265.0 EU      | 323.8 EU      | 187.1 EU      | 378 EU        |
| Median                    | 650 EU        | 812 EU        | 1507 EU       | 2060 EU       |
| Standard deviation        | 459.0 EU      | 560.8 EU      | 324.0 EU      | 534.6 EU      |
| Number of vials           | 3             | 3             | 3             | 2             |
| Confidence interval (95%) | ±519.4 EU     | ±634.6 EU     | ±366.7 EU     | ±740.9 EU     |

| Extraction procedure      | T/U/LPS 200 | T/S/LPS 200 | P/U/LPS 200 | P/S/LPS 200 |
|---------------------------|-------------|-------------|-------------|-------------|
| Mean                      | 152.3 EU    | 90.7 EU     | 44.3 EU     | 104.3 EU    |
| Standard error mean       | 20.7 EU     | 26.7 EU     | 2.8 EU      | 43.8 EU     |
| Median                    | 143 EU      | 109 EU      | 42 EU       | 72 EU       |
| Standard deviation        | 35.9 EU     | 46.3 EU     | 4.9 EU      | 75.9 EU     |
| Number of vials           | 3           | 3           | 3           | 3           |
| Confidence interval (95%) | ±40.6 EU    | ±52.4 EU    | ±5.6 EU     | ±85.8 EU    |

| Extraction procedure      | T/U/<br><i>P.aeruginosa</i> | T/S/<br><i>P.aeruginosa</i> | P/U/<br><i>P.aeruginosa</i> | P/S/<br><i>P.aeruginosa</i> |
|---------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Mean                      | 1244 EU                     | 2072.8 EU                   | 259.2 EU                    | 326.8 EU                    |
| Standard error mean       | 349.6 EU                    | 1116.1 EU                   | 201.2 EU                    | 15.6 EU                     |
| Median                    | 1580 EU                     | 1235 EU                     | 63.3 EU                     | 323.6 EU                    |
| Standard deviation        | 605.5 EU                    | 1933.1 EU                   | 348.4 EU                    | 27.0 EU                     |
| Number of vials           | 3                           | 3                           | 3                           | 3                           |
| Confidence interval (95%) | ±685.2 EU                   | ±2187.5 EU                  | ±394.3 EU                   | ±30.6 EU                    |

| Extraction procedure      | T/U/Dust  | T/S/Dust  | P/U/Dust  | P/S/Dust |
|---------------------------|-----------|-----------|-----------|----------|
| Mean                      | 610.3 EU  | 283.7 EU  | 460 EU    | 166.7 EU |
| Standard error mean       | 217.9 EU  | 72.3 EU   | 153.7 EU  | 50.4 EU  |
| Median                    | 721 EU    | 341 EU    | 430 EU    | 190 EU   |
| Standard deviation        | 377.4 EU  | 125.3 EU  | 266.3 EU  | 87.4 EU  |
| Number of vials           | 3         | 3         | 3         | 3        |
| Confidence interval (95%) | ±427.0 EU | ±141.7 EU | ±301.3 EU | ±98.9 EU |

T = Tween 20,

P = TAP buffer,

U = sonication,

S = shaking

## 6.2 FIGURES

Recovered endotoxin on  $\frac{1}{2}$  filter pieces is shown in Figure 6-1 till

**FIGURE 6-11 ACTIVITY MEASURED ON  $\frac{1}{2}$  SYNTHETIC FIBER FILTER WITH SONICATION AND TAP**

. For explanation see 3.1.1. No value express filter with failed spikes, 0.0 EU indicate a recovered activity below the detection limit of the LAL test (<0.005 EU/ml).

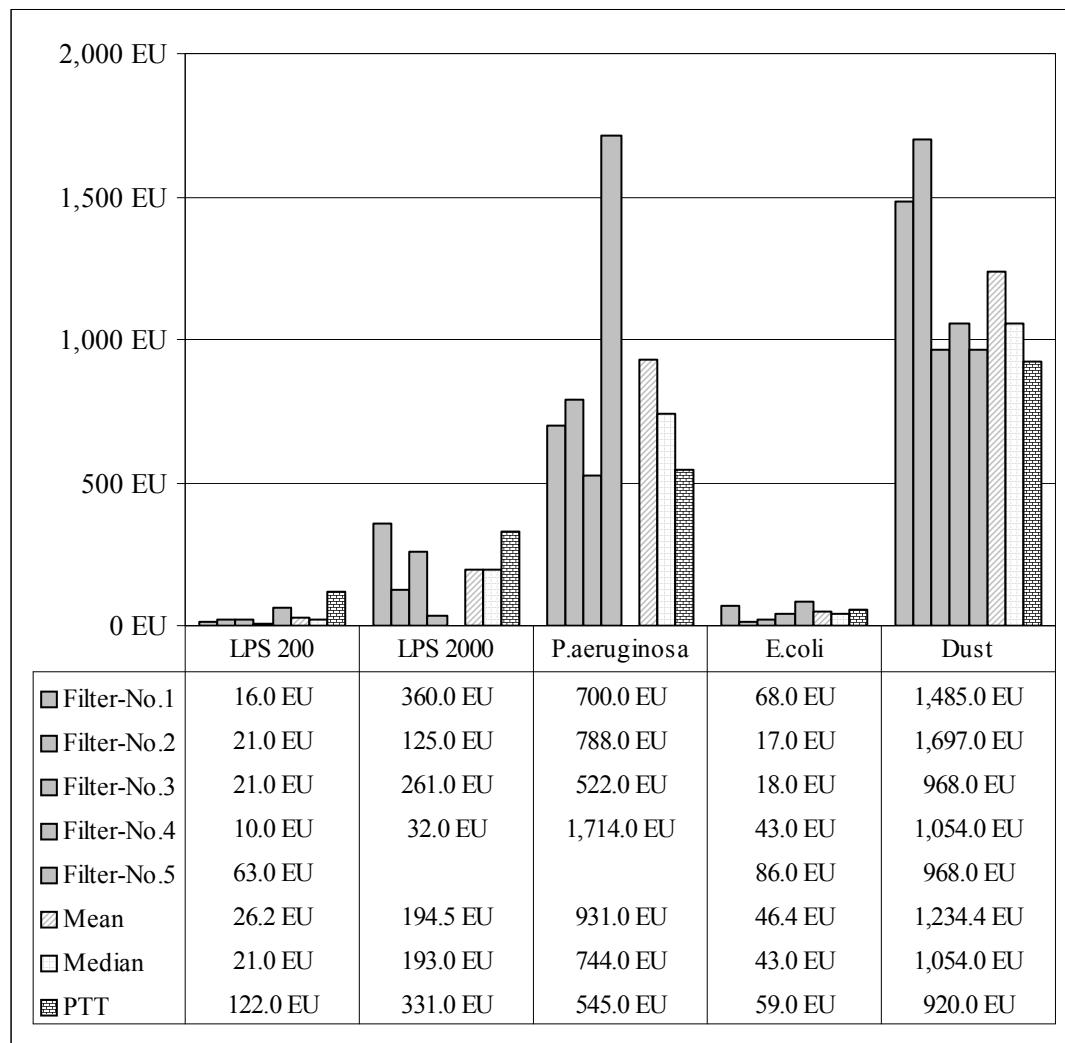
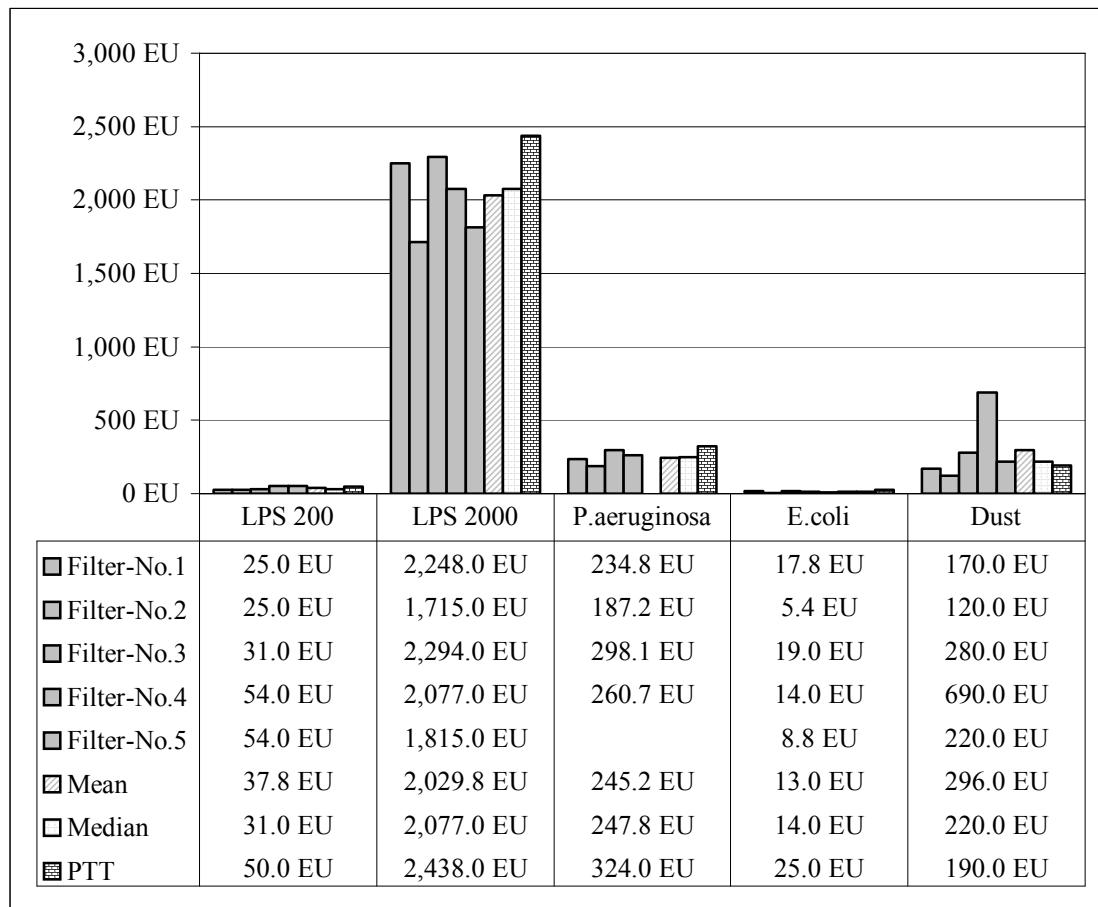
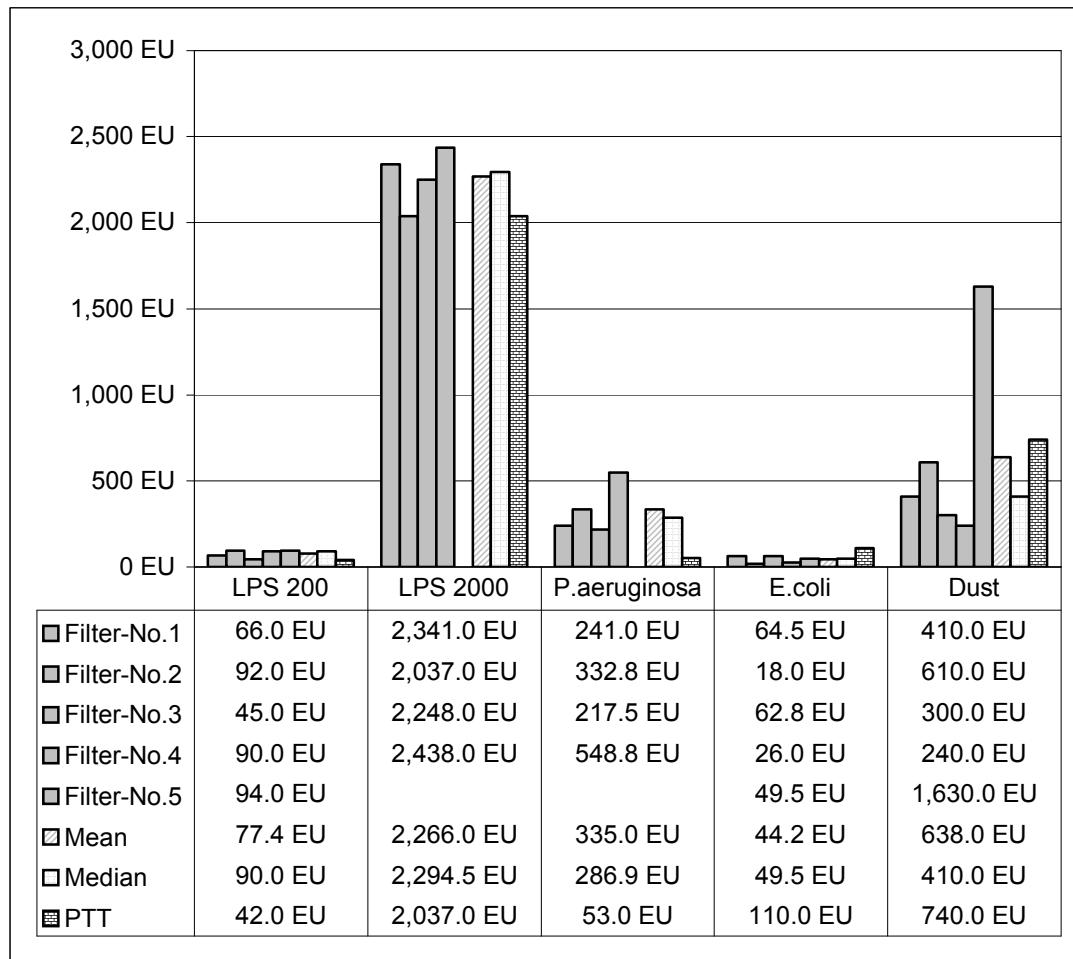


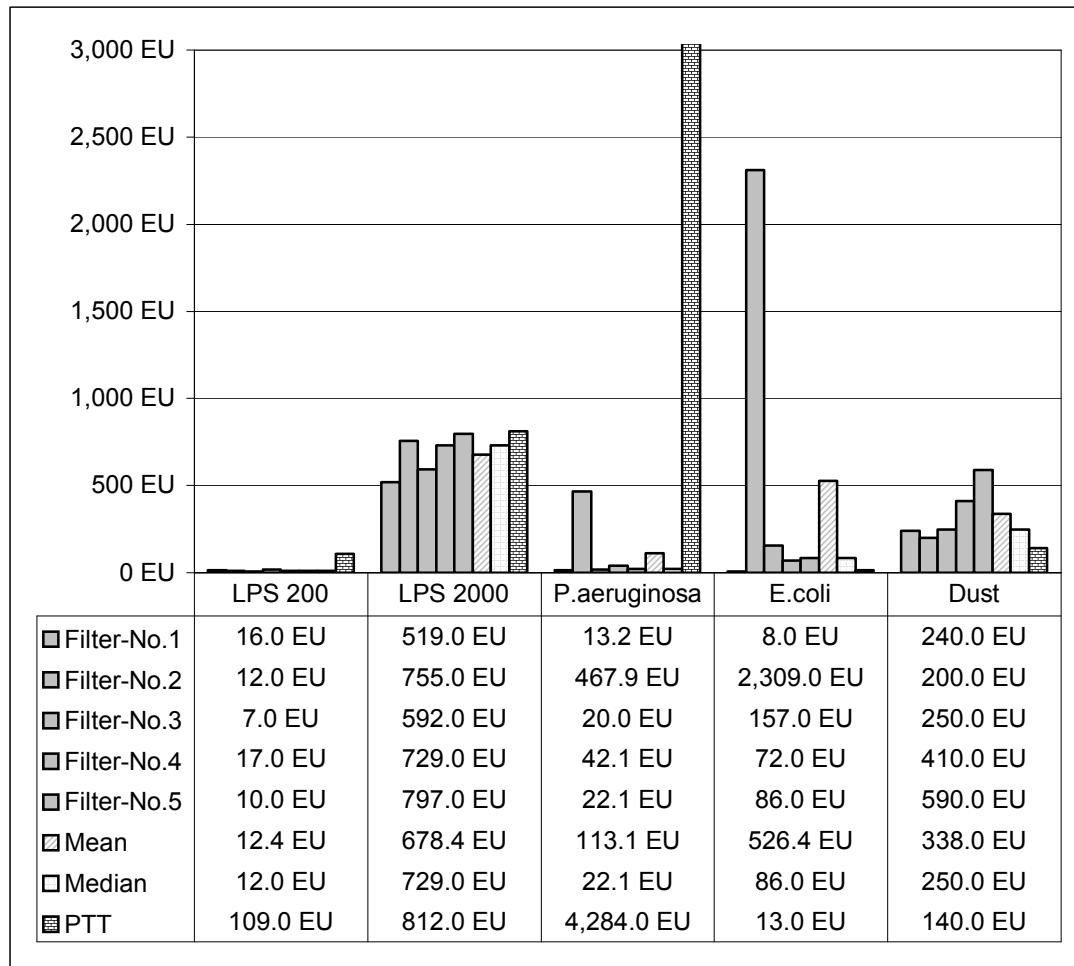
FIGURE 6-1 ACTIVITY MEASURED ON  $\frac{1}{2}$  GLASS FIBER FILTER WITH SONICATION AND TWEEN



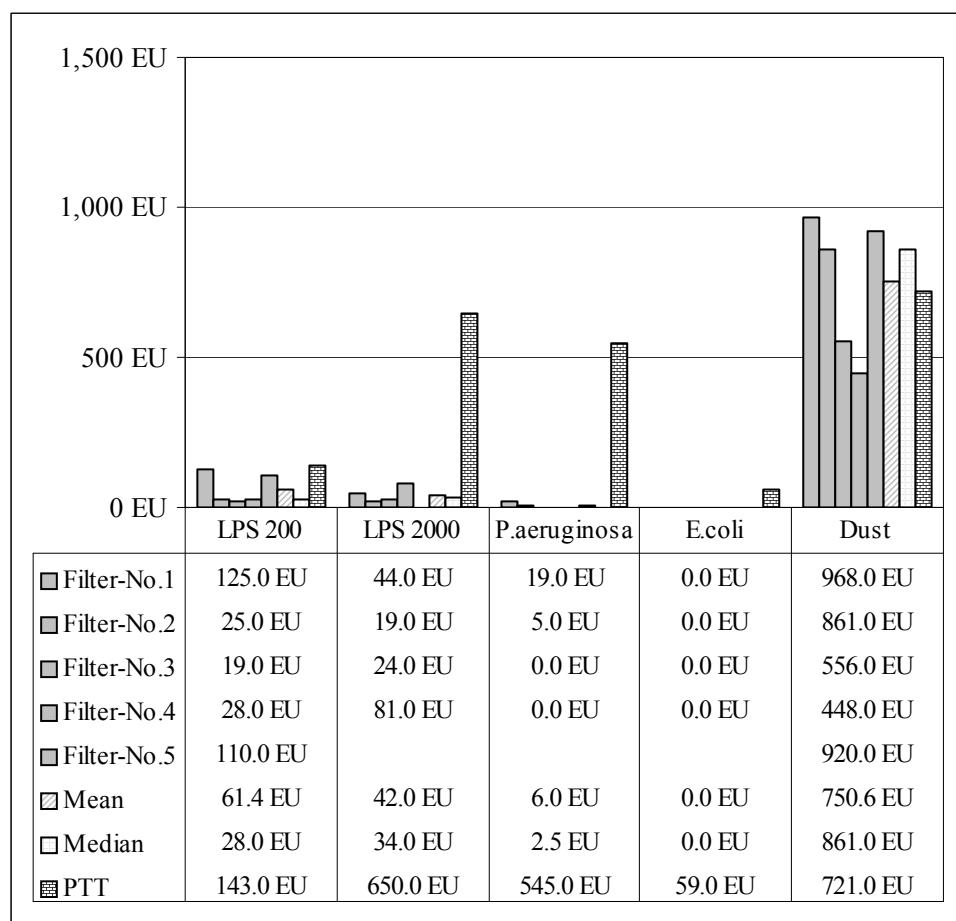
**FIGURE 6-2 ACTIVITY MEASURED ON  $\frac{1}{2}$  GLASS FIBER FILTER WITH SHAKING AND TAP**



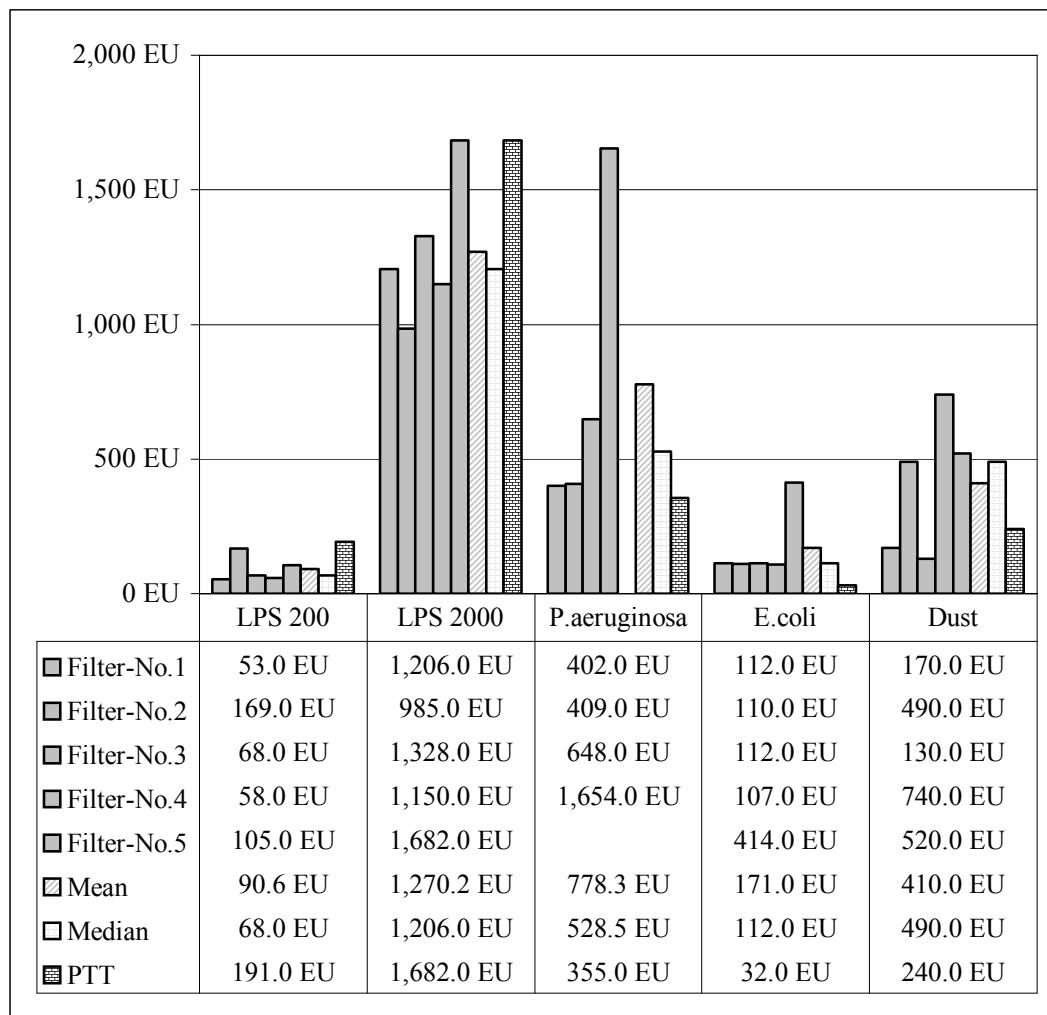
**FIGURE 6-3 ACTIVITY MEASURED ON  $\frac{1}{2}$  GLASS FIBER FILTER WITH SONICATION AND TAP**



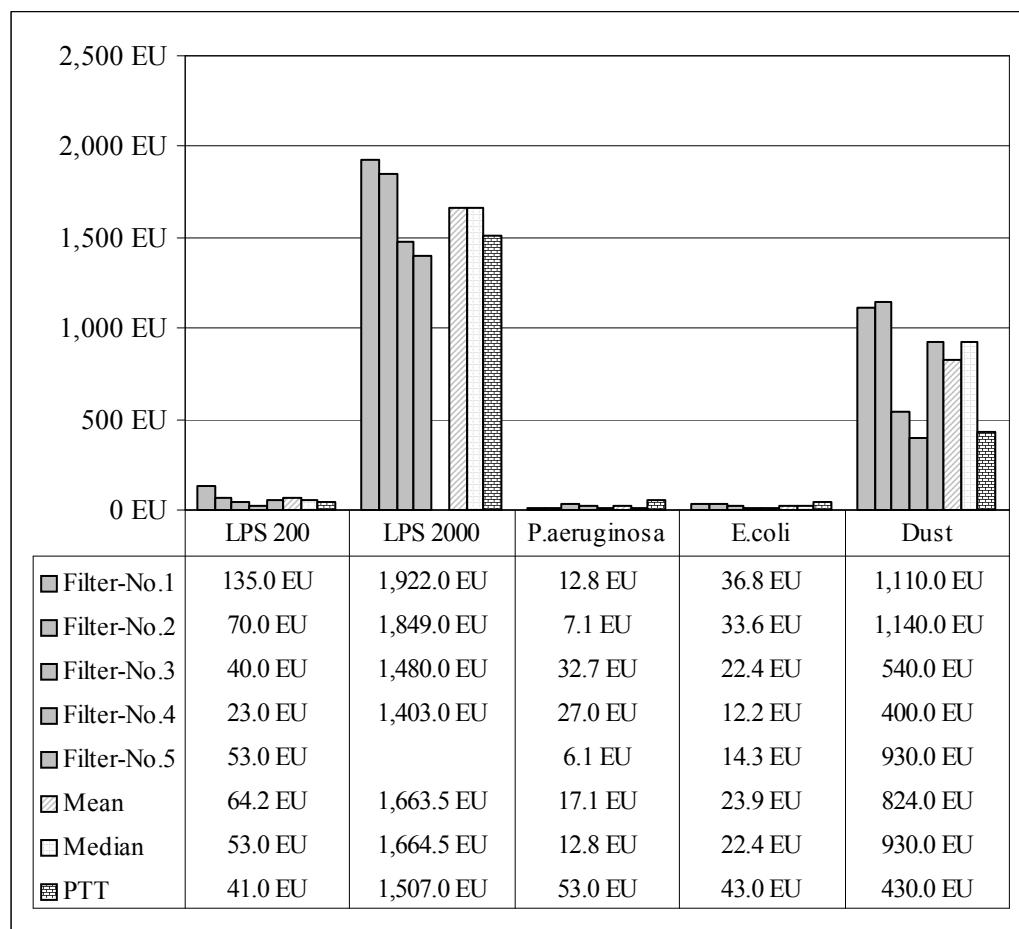
**FIGURE 6-4 ACTIVITY MEASURED ON 1/2 CELLULOSE FIBER FILTER WITH SHAKING AND TWEEN**



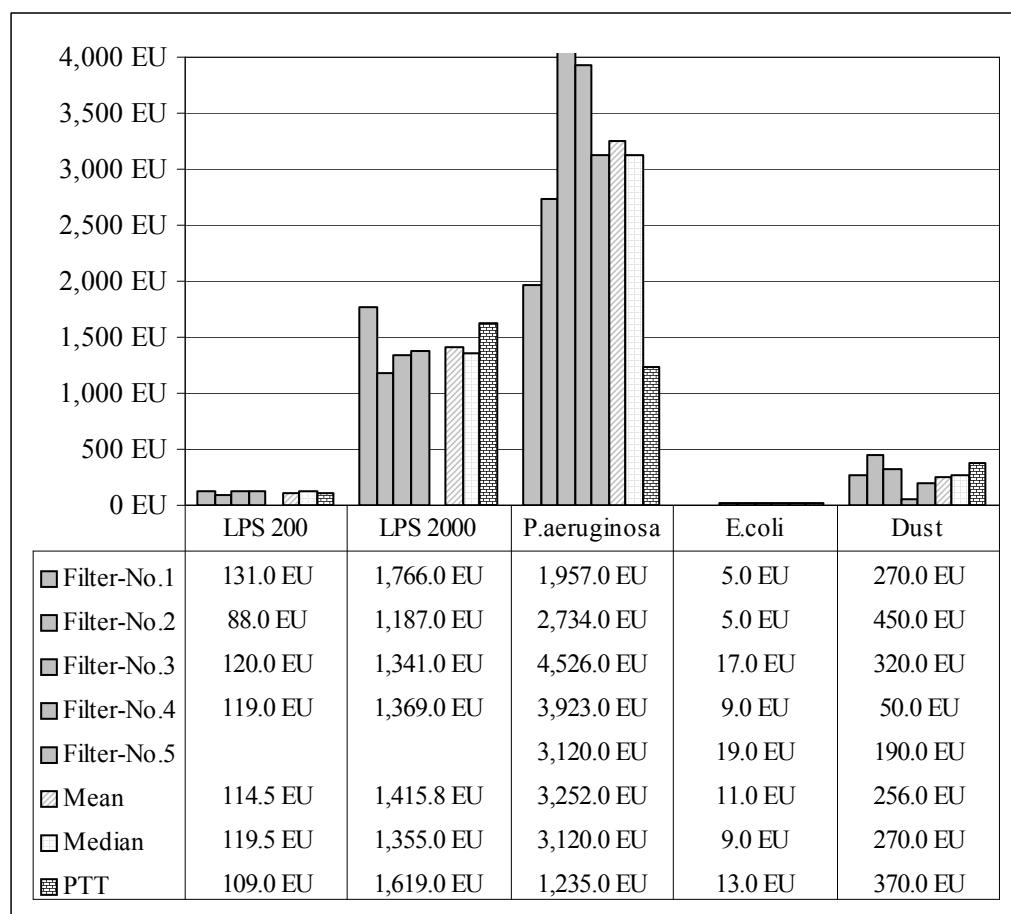
**FIGURE 6-5 ACTIVITY MEASURED ON  $\frac{1}{2}$  CELLULOSE FIBER FILTER WITH SONICATION AND TWEEN**



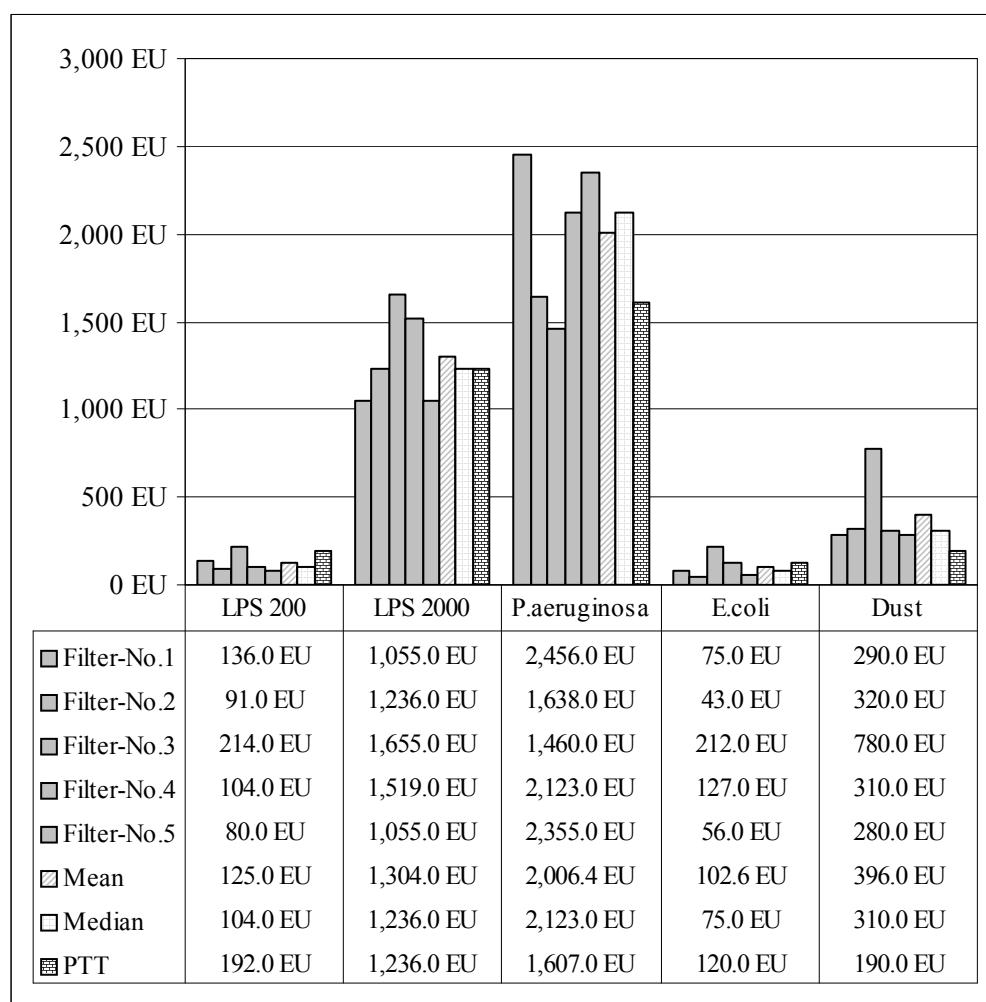
**FIGURE 6-6 ACTIVITY MEASURED ON  $\frac{1}{2}$  CELLULOSE FIBER FILTER WITH SHAKING AND TAP**



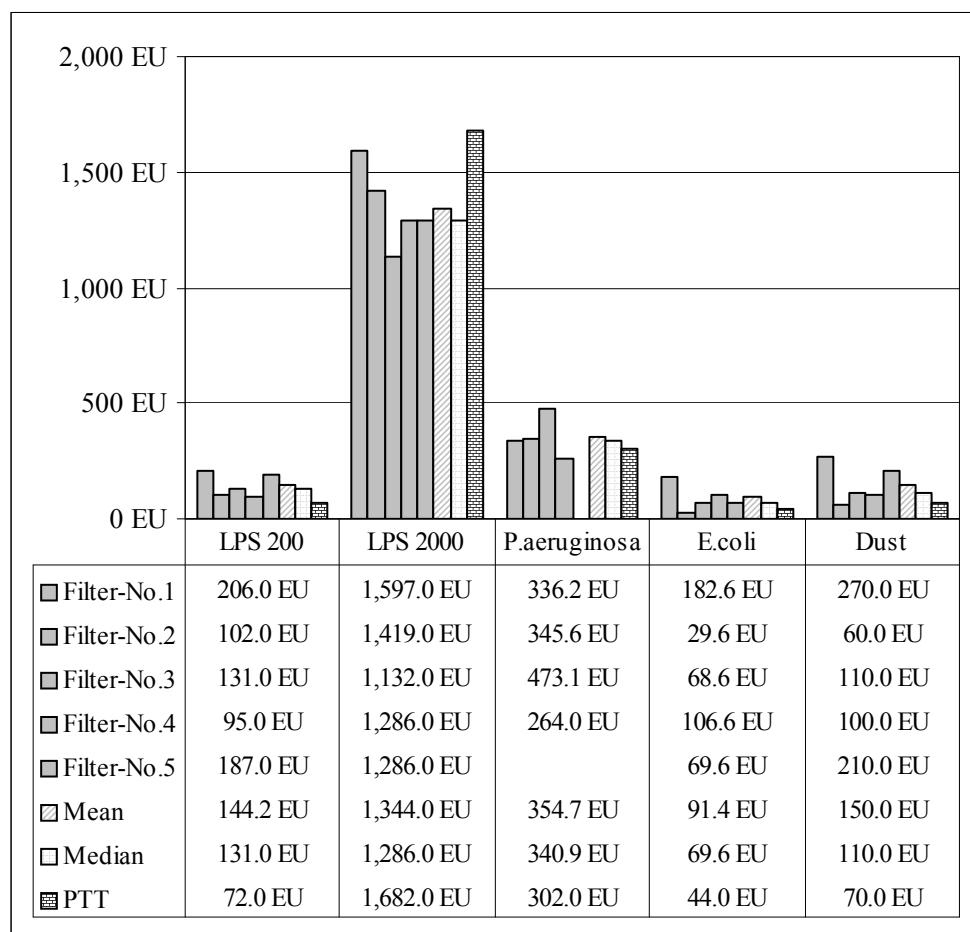
**FIGURE 6-7 ACTIVITY MEASURED ON  $\frac{1}{2}$  CELLULOSE FIBER FILTER WITH SONICATION AND TAP**



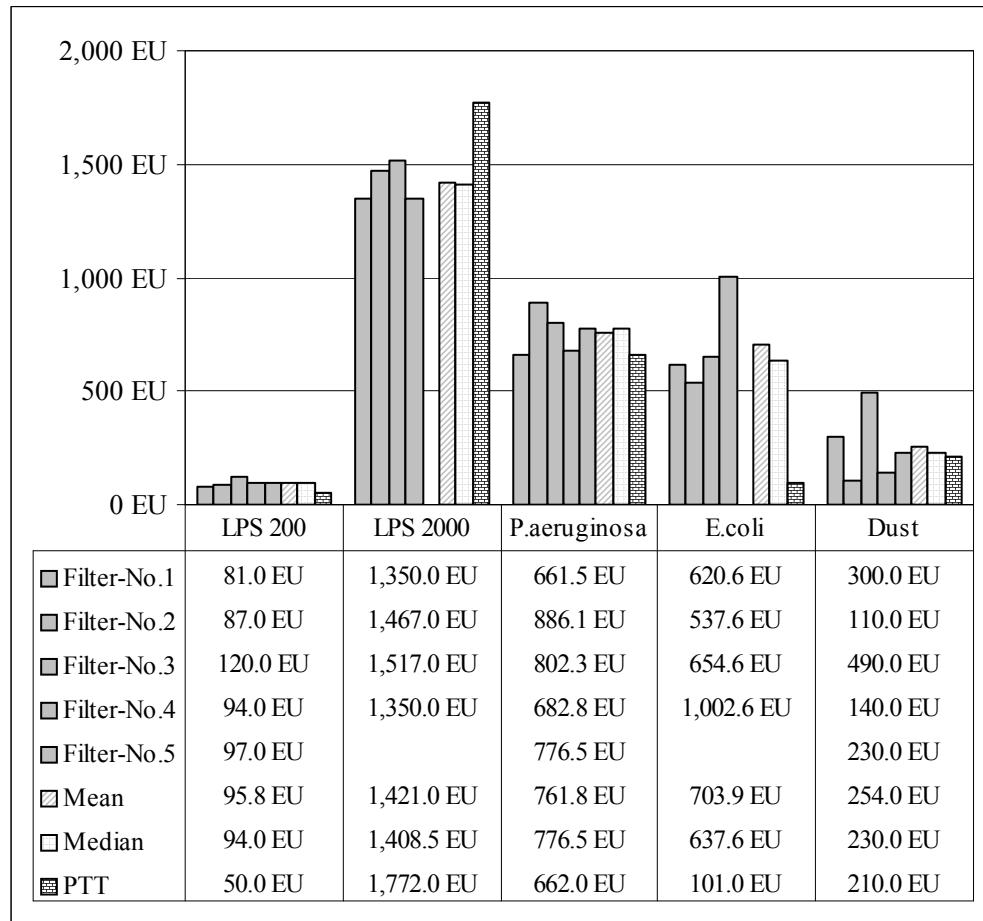
**FIGURE 6-8 ACTIVITY MEASURED ON 1/2 SYNTHETIC FIBER FILTER WITH SHAKING AND TWEEN**



**FIGURE 6-9 ACTIVITY MEASURED ON 1/2 SYNTHETIC FIBER FILTER WITH SONICATION AND TWEEN**



**FIGURE 6-10 ACTIVITY MEASURED ON ½ SYNTHETIC FIBER FILTER WITH SHAKING AND TAP**



**FIGURE 6-11 ACTIVITY MEASURED ON 1/2 SYNTHETIC FIBER FILTER WITH SONICATION AND TAP**